IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

WRIT PETITION (C) NO. _____ / 2022

DIST: MUMBAI

Shri. Dilip Lunawat

.....Petitioner

Versus

Serum Institute of India Pvt. Ltd. & Ors.

.....Respondents

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I

IN THE HIGH COURT OF JUDICATURE AT BOMBAY

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WRIT PETITION (C) NO. _____ / 2022

DIST: MUMBAI

Shri. Dilip Lunawat **.....Petitioner**

Versus

Serum Institute of India Pvt. Ltd. & Ors. **.....Respondents**

SYNOPSIS

Sr. No.	Dates	Particulars
1.		The petitioner is father of deceased Dr. Snehal Lunawat, who was a doctor and Senior lecturer at SMBT Dental College & Hospital at Dhamangaon near Igatpuri in Nashik.
2.		In the initial days of Corona Pandemic caused due to SARS-CoV-2 the health workers were asked to get corona vaccines. The petitioner's daughter who was a doctor was also compelled to take vaccine at the college (she relied on the DCGI, AIIMS AND WHO experts). Through various authorities the petitioner's daughter was assured that, the corona vaccines are completely

III

		safe and having no risk and threat to her body.
3.	**04.01.2021**	Interview given to NDTV on 4th January, 2021 by Respondent No. 7, Dr. V.G. Somani, Drug Controller General of India, it is categorically mentioned that, the vaccine are 110% safe.
4.	**25.04.2021**	Also interviews are given by Respondent No. 8, Dr. Randeep Guleria Director of AIIMS, Delhi and others. They were asking everyone to take vaccines stating that, the vaccines are completely safe.
5.	**15.12.2021**	State of Maharashtra is also made clear in a recent affidavit dated 15.12.2021 filed before Hon'ble Bombay High Court. In the said affidavit by Dr. Sadhana Tayade, Director of Health Services, Public Health Department, they are relying on FAQ prepared by U.P. Government. There it is mentioned that for any serious or severe side effects there is definite treatment for each such serious effects.
6.	**28.01.2021**	Due to such false narrative about complete safety of vaccine Petitioner's daughter took the vaccine.
7.	**01.03.2021**	Due to side effects of vaccine the Petitioner's daughter died.

III

8.	**02.10.2021**	Central Government's AEFI Committee admitted that the death of Petitioner's daughter was due to side effects of Covishield vaccine.
9.		The petitioner have filed this petition to give justice to his daughter, to save the life of many more people which are likely to be murdered due to such unlawful activities of the Respondent authorities and to get compensation from the state which later can be recovered from the guilty officers and vaccine manufacturing companies.
10.		Hence this petition.

Acts to be referred to:

1. Constitution of India.

2. Indian Penal Code 1860.

3. Disaster Management Act, 2005.

Advocate for Petitioner

Petitioner

(1)

IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

WRIT PETITION (C) NO. _____ / 2022

DISTRICT:- NASHIK

Under Article 226 of constitution of India.

In the matter of admission by the Government's AEFI Committee that the death of Petitioner's daughter Dr. Snehal Lunawat due to side effects of vaccines;

And

In the matter of giving directions from proper prosecutions to prevent further loss of lives;

And

BEFORE ME

25/01/2022

GANGADHAR RAMJI VAIDYA
Advocate, Notary Govt. of India
Area- Aurangabad District
Mob No.-8390089343
Reg NO 15503

(2)

In the matter of directions for granting compensation to the petitioner and his family.

Shri. Dilip Lunawat)
)
)
)

..... Petitioner

1. Serum Institute of India Pvt. Ltd.)
Mr. Adar C. Poonawalla (CEO))
212/2, Soli Poonawalla Rd, JJC Colony,)
Suryalok Nagari, Hadapsar,)
Pune, Maharashtra 411 028.)

2. Bill Gates)
Partner of Serum Institute,)
For manufacturing Covishield,)
Having address at:)
212/2, Soli Poonawalla Rd, JJC Colony,)
Suryalok Nagari, Hadapsar,)
Pune, Maharashtra 411 028.)

3. Union of India)
Through Chief Secretary)
To the Government of India)
New Delhi 1100 01.)

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4. State of Maharashtra)
Through Chief Secretary,)
Maharashtra State,)
Mantralaya, Mumbai – 400 023.)

5. Ministry of Health & Family Welfare)
Government of India)
Room No. 348; 'A' Wing,)
Nirman Bhavan,)
New Delhi-110 011.)

6. Drug Controller General of India)
FDA Bhawan, Kotla Road,)
New Delhi 110 002.)

7. Dr. V.G. Somani)
Drug Controller General of India)
DA Bhawan, Kotla Road,)
New Delhi 110 002.)

8. Dr. Randeep Guleria)
Director, AIIMS, New Delhi.)
Director, AIIMS, New Delhi.)
All India Institute of Medical Sciences)
Ansari Nagar, New Delhi – 110 029.)

..... Respondents

THE HON'BLE THE CHIEF JUSTICE AND
OTHER HON'BLE PUISNE JUDGES OF

BEFORE ME
25/01/2011
GANGADHAR RAMJI VAIDYA
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Reg No 15503

(4)

HIGH COURT OF JUDICATURE AT BOMBAY

THE HUMBLE PETITION OF THE PETITIONER ABOVENAMED

MOST RESPECTFULLY SHEWETH:

1. That, the petitioner's daughter was a doctor and Senior lecturer at SMBT Dental College & Hospital at Dhamangaon near Igatpuri in Nashik.

2. That, in the initial days of Corona Pandemic caused due to SARS-CoV-2 the health workers were asked to get corona vaccines.

3. That, the petitioner's daughter who was a doctor was also compelled to take vaccine at the college (she relied on the **DCGI, AIIMS AND WHO** experts).

4. Through various authorities the petitioner's daughter was assured that, the corona vaccines are completely safe and having no risk and threat to her body.

5. In the interview given to **NDTV on 4th January, 2021** by Respondent No. 7, Dr. V.G. Somani, Drug Controller General of India, it is categorically mentioned that, the vaccine are 110% safe.

The relevant portion published in the news reads thus;

> *"Drug Controller General of India VG Somani said, "We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe".*

Link:-

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https://www.ndtv.com/india-news/oxford-covid-19-vaccine-bharat-biotechs-covaxin-get-final-approval-by-drug-regulator-will-be-indias-first-vaccines-2347053

A copy of detailed news article is marked and annexed herewith at "**Exhibit – A**".

6. Similar interviews are given by Respondent No. 8, Dr. Randeep Guleria Director of AIIMS, Delhi and others. They were asking everyone to take vaccines by stating that, the vaccines are completely safe.

Interview given by the Dr. Randeep Guleria is available on YouTube.

Link:-

https://fb.watch/7u26q6CL59/

7. That, on the basis of such false narratives and misrepresentation by the senior authority like Dr. V.G. Somani and others, and its implementation by the state authorities without any proper verification, the health workers like petitioner's daughter was compelled to get vaccine.

8. That, the stand of State of Maharashtra is also made clear in a recent affidavit dated **15.12.2021** filed before Hon'ble Bombay High Court. In the said affidavit by Dr. Sadhana Tayade, Director of Health Services, Public Health Department, they are relying on Frequently Asked Questions which are prepared by U.P. Government. There it is mentioned that for any serious or severe side effects there is definite treatment for each such serious effects.

Said Question No. 16 reads thus;

> ***"What are the common side effects that I can expect after Vaccination?***

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Fever, headaches, body aches, fatigue, injection site pain are the common side effects, and they are manageable by a short course of Paracetamol. Most resolve by 2-3 days. You are observed for 30 minutes after receiving the dose, for any serious or severe effects, and even though they are rare to occur, there is definite treatment for each such serious effect."

A copy of the said affidavit dated **15.12.2021** is marked and annexed herewith at "**Exhibit – B**".

9. Due to such false narrative about complete safety of vaccines, my daughter took **Covishield** vaccine on **28th January, 2021.**

A copy of the vaccination certificate of Dr. Snehal Lunawt is marked and annexed herewith at "**Exhibit C".**

10. That, due to the side effects of vaccines the complainant's daughter died on **1st March, 2021.**

11. The Central Government's AEFI committee on **2nd October, 2021** admitted that the death of complainant's daughter was due to side effects of Covishield vaccine.

A copy of communication received from AEFI committee is marked and annexed herewith at "**Exhibit D**".

12. Hence, this petition is being filed to give justice to my daughter and in order to save the life of many more people which are likely to be murdered due to such unlawful activities of the Respondent authorities.

BEFORE ME
25/11/2021
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13. So far as the prosecution of accused are concerned, it is made clear that the Awaken India Movement has taken the cause for punishing the guilty and therefore the petitioner is not making the said prayers in the petition.

14. That, the chronology and details of the death of the petitioner's daughter from vaccination and the hardship suffered by the petitioner's family are mentioned in the letter written by my son Shri. Shubham Dilip Lunawat on **13th April, 2021** to Ms. Malini Aisola, the Co-convenor, **All India Drug Action Network (AIDAN)**. Said letter reads thus;

> *"To*
>
> *Ms. Malini Aisola*
>
> *Co-Convenor*
>
> *All India Drug Action Network (AIDAN)*
>
> *13 April 2021*
>
> *I am Shubham Lunawat, brother of deceased Dr. Snehal Lunawat who was working in SMBT College, Nasik as a lecturer.*
>
> *My sister took her first dose of Covishield on 28th January 2021 in Nasik. On 5th of February she had a headache. She showed it to the doctors who diagnosed a mild migraine for which she took medicines and felt better. On 5th Feb evening, she came to Aurangabad from where she traveled to Delhi for attending a workshop in Gurgaon. She reached Gurgaon on 6th February afternoon and on the midnight of 7th Feb at 2am, she had multiple episodes of vomiting till morning 8am with fatigue.*

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Reg No. 13503

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She was rushed to nearby Aryan hospital, Gurgaon where they said there might be bleeding in the brain and suspected venous sinus thrombosis. As there was no neurosurgeon available there, we rushed her to the Paras hospital, Gurgaon. She was hospitalised there for 14 days.

She had bleeding, clot formation with low platelets which are all signs of the same condition linked to Astra Zeneca and Covishield vaccine in foreign countries and few in India now. Doctors detected venous sinus thrombosis which was followed by intracranial brain hemorrhage. They performed craniotomy and clot removal surgery. Thereafter she was on a ventilator for 14 days in Gurgaon but her condition did not improve.

She had been tested several times for COVID-19 from the date of admission till the 14th day of her admission to hospital. The results were negative.

We brought her through an air ambulance to United Citgma hospital in Aurangabad. She continued to be on the ventilator for 8 days but condition did not improve. She passed away on 1st March.

We would like your help in bringing our case to the notice of the authorities as my sister has been the victim of fatal side effects of the Covishield vaccine. We want to save future lives.

I have earlier written to several offices including DHO Aurangabad, FDA Haryana and District Immunization

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Officer, Gurgaon and Drug Controller General of India (DCGI). I even tried to inform the highest authorities by writing to the Health Minister of Maharashtra and the Union Health Minister and also making a request through the PMO grievance portal.

Today, I received a reply from the Haryana FDA that conveyed that because notification of an adverse event after vaccination is the responsibility of the district where vaccination took place, the Civil Surgeon in Gurugram will be writing to the District officials in Nasik to report the case. This means that in spite of so many days passing since my sister's condition first deteriorated, weeks of her being hospitalised and more than a month since her demise, her case has not been reported to the government?

My other sister, Samruddhi, had spoken to the incharge of the vaccination drive, Dr. Nobel Gomez, SMBT institute, Nasik over the phone in March. At that time, he immediately said that the issue was not due to vaccination. When she said that this was in fact a matter of discussion, and that we wanted to report it to the Government Medical Authorities and requested for his help, he did not reply to our concern.

My father (the petitioner) had even corresponded with the Serum Institute of India, the manufacturer of Covishield Vaccine asking for help and research in my sister's case, as the doctors had expressed a doubt about the side effect of such vaccination in my sister's body on 9th February, 2021 i.e., immediately the next day after the second operation was

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carried out. But the company completely denied helping us and dismissed our message saying that my sister's condition was a coincidence and was not due to the vaccine. The full conversation with the ***Serum Institute of India*** *is produced in Para No. 15.4.*

Therefore, I have till date not received any confirmation that my sister's case has been duly reported to the authorities that are looking into adverse events of vaccines. I learned from newspaper reports that a governmental committee is looking into vaccine adverse effects. I feel it is important that it can take a look at my sister's case which can also provide guidance and safety measures on vaccination to save similar further deaths of others.

Please see below I am attaching her case summary and some of the letters that I have sent.

Request you to help us urgently

Regards,

Shubham Dilip Lunawat

"Saubhagya", Tirupati garden
Tapadiya Nagar Darga Road
Aurangabad, Maharashtra
Phone: 8668606224/ 9325620758
Email: shubhamlunawat98@gmail.com"

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15. That, the complicity of **Serum Institute and its officers** is ex-facie clear from the very fact that, they gave a false response to the email that there is no such side effect found in clinical trials of the Covishield.

15.1. First E-mail was sent by Dilip Lunawat to Serum Institute on **9th February, 2021** reads thus;

> ***Subject: Covishield vaccination and impact.***
>
> *Dear sir, my daughter Dr. Snehal Dilip Lunawat - have taken the vaccination on 27/01/2021 at SMBT College,Nasik and thereafter there was minor headache and fever on next day but on 4th of February she had again severe headache, vomitting hence after checking in college medical departments on 5th, she has been given medicine. She came to Aurangabad on 5th night and further for her certificate conference she came to Delhi by flight reached @3.30 pm, but in the same late night she had severe headache and unstoppable vomitting and due to weakness, she has to pickup by two/three people and send for hospitalisation in Gurgaon. I am enclosing the case summary in pdf for your research department.I would like to study by your research department and diagnosis the case.Similar cases has been observed in USA. I hope you will do the needful for betterment of the society at large. If any further information required you can contact me. Please note this is not a complaint but whatever corrective actions required should be taken. With regards. Dilip k Lunawat 9225752831 Sent from RediffmailNG on Android*

BEFORE ME

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Area, Aurangabad District
Regd No. 15503

(12)

15.2. The reply dated **10th February, 2021** given by **Dr. Chetanraj Bhamare of Serum Institute, Pune** reads thus;

> *"Dear Mr. Lunawat,*
> *We acknowledge the receipt of your report of adverse event.*
> *For the assessment of the case kindly provide the batch details of vaccine administered.*
> *Kindly note that, Covishield does not cause transverse sinus thrombosis or infarcts.*
> *Please refer the details of COVISHIELD available online at https://www.seruminstitute.com/product_covishield.php.*
>
> *Regards,*
> ***Dr. Chetanraj Bhamare, MBBS MD***
> *Safety Physician,*
> *Clinical Research and Pharmacovigilance Dept,*
> *Serum Institute of India Pvt. Ltd., Pune (India)."*

15.3. The email dated **13th February, 2021** sent by Dilip K. Lunawat reads thus;

> *"Dear sirs, this has reference to our earlier emails, we are enclosing the medical case summary of my daughter Dr Snehal Dilip Lunawat and given below the cases links around india, which are similar to our case.*
>
> *https://www.cnbctv18.com/healthcare/16-deaths-reported-among-vaccine-recipients-govt-says-not-linked-to-vaccine-patient-groups-demand-more-data-8199491.htm*

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25/1/2021
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Reg No 15509

https://timesofindia.indiatimes.com/city/bengaluru/karnataka-asha-worker-dies-12-days-after-vaccination-in-belagavi/articleshow/80712499.cms

we again request you to find out by your research team to stop further deaths due to vaccination. If you have any research done on thrombosis due to covishield please share. Our patient is critical and suffering. It might help us. Thanks"

15.4. The reply dated **15th February, 2021** given by **Dr. Chetanraj Bhamare of Serum Institute, Pune** reads thus:

"Dear Mr. Lunawat,

Thank you for sharing medical case summary of Dr. Snehal.

As we could find in the news reports, you have shared, the deaths were not caused by vaccine and were the coincidental events with vaccination. The govt. has also investigated and concluded the cases as not related to the vaccination. In any large immunization campaign such coincidental events and deaths do occur, they are not caused by the vaccine but are actually a part of background rate of events.

As informed to you earlier, Covishield do not cause thrombosis or any other cardiovascular events.

The known adverse reactions are injection site reactions, fever, headache, malaise, fatigue, etc. The majority of adverse reactions are mild to moderate in severity and usually resolved within a few days of vaccination.

BEFORE ME
25/01/2021
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Please refer the details of COVISHIELD available online at https://www.seruminstitute.com/product_covishield.php.

Kindly consult your physician for the management of the case

Dr. Chetanraj Bhamare, MBBS MD
Safety Physician,
Clinical Research and Pharmacovigilance Dept,
Serum Institute of India Pvt. Ltd., Pune (India). "

15.5. Shri. Elangbam Robert Singh, Director (RCH), Ministry of Health & Family Welfare vide his order dated **05.10.2021** provided the information. The Question No. 1 proves the dishonesty and malafides of Serum Institute of India.

The Question No. 1 in reply given by Health Ministry reads thus;

*"**Point 1:** Details of all the Cases of specific embolic and thrombotic events in combination with low levels of blood platelets (thrombocytopenia) found in the patients all over India reported with you post Covishield vaccination. Details should contain Name, Age, Gender, Place, Hospital name.*

***Information:** Two suspected cases of embolic and thrombotic events in combination with low levels of blood platelets (thrombocytopenia) following Covishield vaccination were identified in 498 cases rapidly reviewed and assessed by medical experts. Both these cases were in females above 50 years of age. Personal details the reported cases are not shared under Section 8(1)(j) of the RTI Act, 2005."*

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A copy of order dated **05.10.2021** given by Ministry of Health & Family Welfare is marked and annexed herewith at "**Exhibit-E**"

16. In the **Economics Times** dated **29.04.2021** and **Times of India** dated **23.04.2021** Dr. Snehal Lunawat's case was published quoting headlines, "WHO to look into death of Indian Doctor post Jab". WHO had ordered investigation which was carried out by the AEFI Committee. For obtaining the investigation reports, Petitioner's family contacted the government officials through various forums such as **INGRAMs, DHO** Aurangabad and the other mentioned authorities as specified in the detailed mail is marked and annexed herewith at "**Exhibit – F**".

But no information was shared with us by any of the Government Officials even after repeated calls, mails and messages. Hence, we filed an RTI on **12.05.2021** asking the government officials to share the investigation reports of Dr. Snehal with us. The RTI was initially rejected by the CPIO and then finally information was shared with us after filing the case with the First Appellate Authority on **05.10.2021.**

A copy of such RTI reply received is marked and annexed herewith at "**Exhibit – E**".

17. That on **9th November, 2021** Canada's Health Department also warned about side effects on Covishield:

Link:-

https://globalnews.ca/news/8362363/astrazeneca-covid-vaccine-autoimmune-disorder-health-canada-update/

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"Health Canada adds autoimmune disorder warning to AstraZeneca, J&J COVID-19 vaccines

Health Canada is updating the labels for the AstraZeneca and Johnson & Johnson COVID-19 vaccines to add immune thrombocytopenia (ITP), an autoimmune condition, as a potential side effect."

18. That, in March 2021, around 18 European countries banned Astrazeneca (Covishield) vaccine due to death caused because of side effects of blood clotting due to vaccination.

Link:-

https://www.aljazeera.com/news/2021/3/15/which-countries-have-halted-use-of-astrazenecas-covid-vaccine

19. That WHO on **26th July, 2021** also warned people about GBS caused due to Covishield.

Link:-

https://www.who.int/news/item/26-07-2021-statement-of-the-who-gacvs-covid-19-subcommittee-on-gbs

20. **State authority was duty-bound to publish the side effects of vaccines and also to publish that there cannot be any force or mandate for taking vaccine as done by the Japan Government. But Respondent No. 4 adopted unlawful, unconstitutional approach.**

20.1. That, Hon'ble High Court in **Master Haridaan Kumar Vs. Union of India 2019 SCC OnLine Del 11929,** it is ruled as under;

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"14. <u>The contention that indication of the side effects and contraindications in the advertisement would discourage parents or guardians from consenting to the MR campaign and, therefore, the same should be avoided, is unmerited. The entire object of issuing advertisements is to ensure that necessary information is available to all parents/guardians in order that they can take an informed decision.</u> The respondents are not only required to indicate the benefits of the MR vaccine but also indicate the side effects or contraindications so that the parents/guardians can take an informed decision whether the vaccine is to be administered to their wards/children.

15. In view of the above, it is directed as under:

(4) MR vaccines will not be administered to those students whose parents/guardians have declined to give their consent. The said vaccination will be administered only to those students whose parents have given their consent either by returning the consent forms or by conforming the same directly to the class teacher/nodal teacher and also to students whose parents/guardians cannot be contacted despite best efforts by the class teacher/nodal teacher and who have otherwise not indicated to the contrary.

(1) <u>Directorate of Family Welfare shall issue quarter page advisements in various newspapers as indicated by the respondents, namely, The Hindustan Times, The Times of India,</u> The Hindu, The Pioneer, The Indian Express, Delhi Tribune, Mail Today, The Asian Age, Navbharat Times,

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*Dainik Jagran, Punjab Kesari, Hindustan, Amar Ujala, Navodaya Times, Hamara Samaj, Pratap, Daur-e-Jadeed, Jathedar, Jan Ekta. The advertisements shall also indicate that the vaccination shall be administered with Auto Disable Syringes to the eligible children by Auxiliary Nurse Midwifery. **The advertisement shall also clearly indicate the side effects and contraindications as may be finalised by the Department of Preventive Medicine, All India Institute of Medical Sciences."***

20.1.1. That the WHO has warned the people getting CoviShield (AstraZeneca) vaccines to be careful as it is causing a serious paralytic disease **GBS (Guillain Barre Syndrome).**

Link:-

https://www.who.int/news/item/26-07-2021-statement-of-the-who-gacvs-covid-19-subcommittee-on-gbs

20.1.2. That, in India, there are Lacs of such cases and around **12,000** vaccine deaths are reported in media. But AEFI committee is not working fairly and properly.

Link:-

https://drive.google.com/file/d/1uikc1a6_KDzUx7HNLrfwaI1NJRt0D_YP/view?usp=sharing

https://docs.google.com/document/d/1LZJDp-ub6BfVt-nnc8daISgemhkRieQG/edit?usp=sharing&ouid=103856627695944525595&rtpof=true&sd=true

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20.2. That the provisions of **Universal Declaration on Bioethics and Human Rights, 2005** also mandate for giving detailed information to public for getting informed consent.

Relevant Articles reads thus;

> *"Article 3 – Human dignity and human rights*
>
> *1. Human dignity, human rights and fundamental freedoms are to be fully respected.*
>
> ***2. The interests and welfare of the individual should have priority over the sole interest of science or society.***
>
> *Article 6 – Consent*
>
> *1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.*
>
> *2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles*

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and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions

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prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 16 – Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Application of the principles

Article 18 – Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

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3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted."

20.3. In **Montgomery Vs. Lanarkshire Health Board [2015] UKSC 11,** it is ruled as under;

"89. Three further points should be made. First, it follows from this approach that the assessment of whether a risk is material cannot be reduced to percentages. The significance of a given risk is likely to reflect a variety of factors besides its magnitude: for example, the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives. The assessment is therefore fact-sensitive, and sensitive also to the characteristics of the patient.

77. These developments in society are reflected in professional practice. The court has been referred in particular to the guidance given to doctors by the General Medical Council, who participated as interveners in the present appeal. One of the documents currently in force (Good Medical Practice (2013)) states, under the heading "The duties of a doctor registered with the General Medical Council":

"Work in partnership with patients. Listen to, and respond to, their concerns and preferences. Give patients the information they want or need in a way they can

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understand. Respect patients' right to reach decisions with you about their treatment and care."

78. Another current document (Consent: patients and doctors making decisions together (2008)) describes a basic model of partnership between doctor and patient:

"The doctor explains the options to the patient, setting out the potential benefits, risks, burdens and side effects of each option, including the option to have no treatment. The doctor may recommend a particular option which they believe to be best for the patient, but they must not put pressure on the patient to accept their advice. The patient weighs up the potential benefits, risks and burdens of the various options as well as any non-clinical issues that are relevant to them. The patient decides whether to accept any of the options and, if so, which one." (para 5)

In relation to risks, in particular, the document advises that the doctor must tell patients if treatment might result in a serious adverse outcome, even if the risk is very small, and should also tell patients about less serious complications if they occur frequently (para 32). The submissions on behalf of the General Medical Council acknowledged, in relation to these documents, that an approach based upon the informed involvement of patients in their treatment, rather than their being passive and potentially reluctant recipients, can have therapeutic benefits, and is regarded as an integral aspect of professionalism in treatment.

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80. In addition to these developments in society and in medical practice, there have also been developments in the law. Under the stimulus of the Human Rights Act 1998, the courts have become increasingly conscious of the extent to which the common law reflects fundamental values. As Lord Scarman pointed out in Sidaway's case, these include the value of self-determination (see, for example, S (An Infant) v S [1972] AC 24, 43 per Lord Reid; McColl v Strathclyde Regional Council 1983 SC 225, 241; Airedale NHS Trust v Bland [1993] AC 789, 864 per Lord Goff of Chieveley). As well as underlying aspects of the common law, that value also underlies the right to respect for private life protected by article 8 of the European Convention on Human Rights. The resulting duty to involve the patient in decisions relating to her treatment has been recognised in judgments of the European Court of Human Rights, such as Glass v United Kingdom (2004) EHRR 341 and Tysiac v Poland (2007) 45 EHRR 947, as well as in a number of decisions of courts in the United Kingdom. The same value is also reflected more specifically in other international instruments: see, in particular, article 5 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, concluded by the member states of the Council of Europe, other states and the European Community at Oviedo on 4 April 1997.

82. <u>In the law of negligence, this approach entails a duty on the part of doctors to take reasonable care to ensure</u>

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<u>that a patient is aware of material risks of injury that are inherent in treatment.</u> This can be understood, within the traditional framework of negligence, as a duty of care to avoid exposing a person to a risk of injury which she would otherwise have avoided, but it is also the counterpart of the patient's entitlement to decide whether or not to incur that risk. The existence of that entitlement, and the fact that its exercise does not depend exclusively on medical considerations, are important. They point to a fundamental distinction between, on the one hand, the doctor's role when considering possible investigatory or treatment options and, on the other, her role in discussing with the patient any recommended treatment and possible alternatives, and the risks of injury which may be involved.

83. The former role is an exercise of professional skill and judgment: what risks of injury are involved in an operation, for example, is a matter falling within the expertise of members of the medical profession. But it is a non sequitur to conclude that the question whether a risk of injury, or the availability of an alternative form of treatment, ought to be discussed with the patient is also a matter of purely professional judgment. The doctor's advisory role cannot be regarded as solely an exercise of medical skill without leaving out of account the patient's entitlement to decide on the risks to her health which she is willing to run (a decision which may be influenced by non-medical considerations). Responsibility for determining the nature and extent of a

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person's rights rests with the courts, not with the medical professions.

87. The correct position, in relation to the risks of injury involved in treatment, can now be seen to be substantially that adopted in Sidaway by Lord Scarman, and by Lord Woolf MR in Pearce, subject to the refinement made by the High Court of Australia in Rogers v Whitaker, which we have discussed at paras 77-73. An adult person of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.

90. Secondly, the doctor's advisory role involves dialogue, the aim of which is to ensure that the patient understands the seriousness of her condition, and the anticipated benefits and risks of the proposed treatment and any reasonable alternatives, so that she is then in a position to make an informed decision. This role will only be performed effectively if the information provided is

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comprehensible. ***The doctor's duty is not therefore fulfilled by bombarding the patient with technical information which she cannot reasonably be expected to grasp, let alone by routinely demanding her signature on a consent form.***

116. As NICE (2011) puts it, "Pregnant women should be offered evidence-based information and support to enable them to make informed decisions about their care and treatment" (para 1.1.1.1). Gone are the days when it was thought that, on becoming pregnant, a woman lost, not only her capacity, but also her right to act as a genuinely autonomous human being."

20.4. But Respondent No.4 and other state authorities failed to perform its duty as per law and vaccinated the public by suppressing the data and it is a case of cheating.

20.4.1. That, recently the Health Ministry of Japan has made Following declaration/orders on their website:

"Consent to vaccination

Although we encourage all citizens to receive the COVID-19 vaccination, it is not compulsory or mandatory. Vaccination will be given only with the consent of the person to be vaccinated after the information provided. Please get vaccinated of your own decision, understanding both the effectiveness in preventing infectious diseases and the risk of side effects. No vaccination will be given without consent. Please do not force anyone in your workplace or those who

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around you to be vaccinated, and do not discriminate against those who have not been vaccinated."

20.4.2. Furthermore, the Government of Japan also asked the citizens to make complain to Human Rights Division if there is any discrimination on the basis of vaccination status.

20.4.3. The government made companies of Covid "vaccines" to warn of dangerous and potentially deadly side effects such as myocarditis. In addition, the country is reaffirming its commitment to adverse event reporting requirements to ensure all possible side effects are documented.

For more details read the article:

https://rairfoundation.com/alert-japan-places-myocarditis-warning-on-vaccines- requires-informed-consent/

Alert: Japan Places Myocarditis Warning on 'Vaccines' - Requires Informed Consent Amy Mek.

20.4.4. That the above declaration is mandatory to all countries across the world because of **Universal Declaration on Bioethics & Human Rights, 2005** and also as per law laid down in **Montgomery's case [2015] UKSC 11, Airdale NHS Trust Vs. Bland (1993) 1 All ER 821, Common Cause Vs. Union of India (2018) 5SCC 1, Registrar General Vs. State of Meghalaya 2021 SCC OnLine Megh 130.**

20.4.5. That as per legal requirements, there should be a mandatory procedure to take written consent of the person before giving him the vaccine. In **Ajay Gautam Vs. Amritsar Eye Clinic & Ors. 2010 SCC OnLine NCDRC 96,** it is observed as under;

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"10. Now, it is to be seen if the opposite party-doctor was entitled to publish such an advertisement or whether it was unethical on his part to do so. In this context, we may notice the injunction of the Medical Council of India under Regulation no. 6.1 of the Code of Ethics Regulations, 2002, which reads as under:

"Chapter 6

6. UNETHICAL ACTS:

A physician shall not aid or abet or commit any of the following acts, which shall be construed as unethical -

6.1 Advertising:

6.1.1 Soliciting of patients directly or indirectly, by a physician, by a group of physicians or by institutions or organisations is unethical. A physician shall not make use of him/her (or his/her name) as subject of any form or manner of advertising or publicity through any mode either alone or in conjunction with others which is of such a character as to invite attention to him or to his professional position, skill, qualification, achievements, attainments, specialities, appointments, associations, affiliations or honours and/or of such character as would ordinarily result in his self aggrandizement. A physician shall not give to any person, whether for compensation or otherwise, any approval, recommendation, endorsement, certificate, report or statement with respect of any drug, medicine, nostrum remedy, surgical, or therapeutic article, apparatus or appliance or any commercial product or article with respect of any property, quality or use thereof or any test,

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demonstration or trial thereof, for use in connection with his name, signature, or photograph in any form or manner of advertising through any mode nor shall he boast of cases, operations, cures or remedies or permit the publication of report thereof through any mode. A medical practitioner is however permitted to make a formal announcement in press regarding the following:

1. On starting practice.

2. On change of type of practice.

3. On changing address.

4. On temporary absence from duty.

5. On resumption of another practice.

6. On succeeding to another practice.

7. Public declaration of charges.

6.1.2 Printing of self photograph, or any such material of publicity in the letter head or on sign board of the consulting room or any such clinical establishment shall be regarded as acts of self advertisement and unethical conduct on the part of the physician. However, printing of sketches, diagrams, picture of human system shall not be treated as unethical".

Clearly the doctor violated the above mentioned Regulation which by itself was unethical conduct and hence constitute deficiency in service.

Moreover, the contents of the advertisement appear to be prima facie misleading to the reader inasmuch as it gives an impression that any defective vision could be corrected to the normal vision of 6/6 at respondent no. 1-hospital by the use of the excimer laser machine acquired by the

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<u>respondent no. 1 & 2</u>. The complainant states that having come across such a misleading advertisement, he contacted respondent no. 2-doctor who also gave assurance and promised that defect in his eye would be fully corrected and cured and only thereafter he agreed to undergo the PRK surgery at the hands of the respondent-doctor. The respondent-doctor denies that he had given any such assurance/promise. The expert medical opinion received from the Rajendra Prasad Centre for Opthalmic Sciences would clearly show that such a claim as was published in the above mentioned advertisement was untenable altogether and, therefore, amounted to representation by the respondent-doctor which could not have been fulfilled.

<u>The respondent-doctor also claimed that he had explained the implications of such a surgery and had obtained the consent of the complainant. As noticed above, the doctor and the hospital have failed to produce the consent form which the complainant had purportedly signed before undergoing the PRK surgery</u>. However, reliance is placed on the format of other consent forms obtained from other patients which contain some admissions on the part of the patients that they had been explained the implications of the procedure.

11. *Having considered the matter in its entirety, we are of the opinion that the finding of the State Commission that the complainant has failed to establish any negligence/deficiency in service on the part of the respondent-doctor and hospital in giving him the treatment by way of PRK surgery is justified on record and needs no*

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interference. However, it has also been established on record that the doctor and the hospital are guilty of adopting unfair trade practice within the meaning of section 2(1)(r) of the Consumer Protection Act, 1986 as well as violating the Code of Ethics Regulations (Regulation no. 6.1) by publishing misleading advertisement. They are also held guilty of not having been able to produce/maintain the record, i.e., consent form said to have been signed by the complainant before undertaking PRK surgery. The complainant is entitled to some reasonable compensation on these two counts.

12. In our view, it would meet the ends of justice if respondents no. 1 & 2 are called upon to pay lumpsum compensation of Rs. 1,00,000/- to the complainant on these counts and a direction is given to respondent no. 1 and the doctor to forthwith withdraw any such advertisement in electronic, print or any other media and desist from doing so in future.

13. In the result appeal is partly allowed and respondent no. 1 & 2 i.e. hospital and doctor are hereby directed to pay lumpsum compensation of Rs. 1,00,000/- to the complainant and also to give an undertaking before this Commission that he will not publish any such advertisement in future within a period of four weeks from the date of receipt of order. However, in case the amount is not paid within the prescribed period, it will carry interest @ 12% p.a."

21. No immunity to Vaccine Manufacturing Companies of India:-

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21.1. That, the Respondent No. 3 Union of India, in its affidavit dated **28.11.2021** submitted before the Hon'ble Supreme Court in the case of **Jacob Puliyel Vs. Union of India in Writ Petition (Civil) No. 607 of 2021** had made it clear that as per Indian Law there is no immunity available to the vaccine manufacturing companies.

The relevant para of the affidavit reads thus;

"*INDEMNIFICATION OF VACCINE MANUFACTURERS*

> *65. No indemnity has been granted and the current legal regime under the New Drugs and Clinical Trials Rules, 2019 and Drugs and Cosmetics Act, 1940 does not contain any such provisions."*

22. **Law of granting compensation in Writ Jurisdiction:**

22.1. That, the law is very well settled by this Hon'ble Court and Hon'ble Supreme Court in catena of judgment that whenever fundamental rights of any persons are violated or if any person lost his/her life due to act of commission and omission on the part of a public servant then the High Court can direct the State Government to pay interim compensation to the victim or their family members under writ jurisdiction and the state can recover the said amount from erring public servant later.

Relied on:- i) **Nambi Narayan Vs. Siby Mathews (2018) 10 SCC 804.**

ii) **Veena Sippy Vs. Narayan Dumbre 2012 SCC OnLine Bom 339.**

iii) **Chairman Railway Board Vs. Mrs. Chandrima Das (2000) 2 SCC 465.**

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iv) **Nina Rajan Pillai Vs. Union of India 2011 (5) AD (Del) 36.**

22.2. In **Sanjeevani Vs. State MANU/MH/0469/2021**, it is ruled as under;

> *"13.... Apex Court in the case of D.K. Basu Vs. State of West Bengal reported in MANU/SC/0157/1997: AIR 1997 Supreme Court 610(1) wherein it has been held thus:-*
>
> *55. Thus, to sum up, it is now a well accepted proposition in most of the jurisdiction, that monetary or pecuniary compensation is an appropriate and indeed an effective and sometimes perhaps the only suitable remedy for redressal of the established infringement of the fundamental right to life of a citizen by the public servants and the Sate is vicariously liable for their acts. The claim of the citizen is based on the principle of strict liability to which the defence of sovereign immunity is not available and the citizen must receive the amount of compensation from the State, which shall have the right to be indemnified by the wrong doer. In the assessment of compensation, the emphasis has to be on the compensatory and not on punitive element. The objective is to apply balm to the wounds and not to punish the transgressor or the offender, as awarding appropriate punishment for the offence (irrespective of compensation) must be left to the Criminal Courts in which the offender is prosecuted, which the State in law, is duly bound to do. The award of compensation in the public law jurisdiction is also without prejudice to any other action like civil suit for damages which is lawfully available to the victim or the*

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heirs of the deceased victim with respect to the same matter for the tortious act committed by the functionaries of the State. The quantum of compensation will, of course, depend upon the peculiar facts of each case and no strait-jacket formula can be evolved in that behalf. The relief to redress the wrong for the established invasion of the fundamental rights of the citizens, under the public law jurisdiction is, thus, in addition to the traditional remedies and not in derogation of them. *The amount of compensation as awarded by the Court and paid by the State to redress the wrong done, may in a given case, be adjusted against any amount which may be awarded to the claimant by way of damages in a civil suit."*

22.3. That in a case of side effects of vaccines, the United States Government has set up the '**National Vaccine Injury Compensation Program**'. In a case of side effects of MMR vaccines the court granted a settlement of 101 Million U.S Dollars (7,50,34,31,400 Crores).

A copy of the news article published in "**metlaw**" is marked and annexed herewith at "Exhibit - G".

22.4. Needless to mention here that, in a recent case of vaccine injury the Government of Singapore granted a compensation of **Rs. 1 Crore 78 Las** to the victim as vaccine cause increase in heart beats.

Link:-

https://greatgameindia.com/pfizer-heart-attack-compensation/

22.5. That, there is another case related with misrepresentation by pharma companies by suppressing the side effects of medicines.

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A copy of AEFI Report & RTI reply by Ministry of Health & Family Welfare marked and annexed herewith at **"Exhibit –H Colly"**

The companies failure to report certain safety data was also taken into consideration. The investigating agency of US at their own investigated and recovered an amount **10.2 Billion** U.S. around **7,57,71,92,40,000** Crore Rupees. The excerpts from the news published on **July 2, 2012** in The United State' Department of Justice.

GLAXOSMITHKLINE TO PLEAD GUILTY AND PAY $3 BILLION TO RESOLVE FRAUD ALLEGATIONS AND FAILURE TO REPORT SAFETY DATA

Largest Health Care Fraud Settlement in U.S. History

> *"1. The United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.*
>
> *2. In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does*

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business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the ***CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.***

Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management.

Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation's healthcare system.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of

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Defense: the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

The company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices.

GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a

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speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended.

Between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug.

The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack).

GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.

It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay $1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million."

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The details of abovesaid report is marked and annexed herewith at "**Exhibit – I**".

22.6. That, the case of Petitioner is on highest footing of getting compensation because here the case is of loss of life. Constitution Bench of Hon'ble Supreme Court in the case of **Anita Kushwaha Vs. Pushap Sadan (2016) 8 SCC 509**, has ruled that the life of Indian Citizen is not less pricy than the life of people in England or anywhere. But in India the rights are more precious.

It is ruled that;

> *"18... Bose, J. emphasised the importance of the right of any person to apply to the court and demand that he be dealt with according to law. He said: (Prabhakar Kesheo case [Prabhakar Kesheo Tare v. Emperor, AIR 1943 Nag 26 : 1942 SCC OnLine MP 78] , SCC OnLine MP para 1)*
>
> *"1. ... **The right is prized in India no less highly than in England, or indeed any other part of the Empire**, perhaps even more highly here than elsewhere; and it is zealously guarded by the courts."*

22.7. That, Hon'ble Civil Court in Pune has granted a compensation of Rs. 100 Crores for defamation of half an hours news mistaken identity. Said fact was also taken in to consideration by Hon'ble Bombay High Court in the case of **Veena Sippy Vs. Mr. Narayan Dumbre & Ors. 2012 SCC OnLine Bom 339**. It is observed as under;

> *"20....We must state here that the Petitioner in person has relied upon an interim order passed by this Court in First Appeal arising out of a decree passed in a suit. The decree was passed in a suit filed by a retired Judge of the Apex*

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Court wherein he claimed compensation on account of act of defamation. Considering the evidence on record, the Trial Court passed a decree for payment of damages of ***Rs. 100/- crores****. While admitting the Appeal and while considering the prayer for grant of stay, this Court directed the Appellant-Defendant to deposit a sum of Rs. 20/- crores in the Court and to furnish Bank Guarantee for rest of the decretal amount as a condition of grant of stay. However, this Court directed investment of the amount of Rs. 20/- crores till the disposal of the Appeal. The interim order of this Court has been confirmed by the Apex Court.*

23....

i. We hold that the detention of the Petitioner by the officers of Gamdevi Police Station from 5th April, 2008 to 6th April, 2008 is illegal and there has been a gross violation of the fundamental right of the Petitioner guaranteed by Article 21 of the Constitution of India.

ii. We direct the 5th Respondent-State of Maharashtra to pay compensation of Rs. 2,50,000/- to the Petitioner together with interest thereon at the rate of 8% per annum from 5th April, 2008 till the realization or payment. We direct the State Government to pay costs quantified at Rs. 25,000/- to the Petitioner. We grant time of six weeks to the State Government to pay the said amounts to the Petitioner by an account payee cheque. It will be also open for the fifth Respondent - State Government to deposit the amounts in this Court within the stipulated time. In such event it will be open for the Petitioner to withdraw the said amount.

BEFORE ME
25/01/2022
GANGADHAR RAMJI VAIDYA
Advocate, Supreme Court of India
Appd. Administrative Director
Mob No. 9820057393
REG NO. 15503

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iii. We clarify that it is open for the State Government to take proceedings for recovery of the amount of compensation and costs from the officers responsible for the default, if so advised.

iv. Petition stands dismissed as against the Respondent No. 4.

vi. We make it clear that it will be open for the Petitioner to adopt a regular remedy for recovery of compensation/damages in addition to the amount directed to be paid under this Judgment.

22.8. That, based on the abovesaid principles and comparing with the seriousness of the loss of life caused and consequential harm caused to the Petitioner, the Petitioner is at least entitled for an interim compensation of Rs. 1000 Crores. For a total compensation of Rs. 10,000 Crores, the Petitioner is going to initiate a separate appropriate legal proceeding which will take some time. But this Hon'ble court, on the basis of settled legal and factual position, can grant interim compensation to the petitioner for the loss of life of Petitioner's daughter.

22.9. That the Petitioner lost her elder daughter. Who was just 33½ years old. His loss can neither be explained in words nor can be compensated in terms of money. Only some sort of succor can be done by awarding compensation. The petitioner's claim for compensation is more intended to put deterrence among other officials and thereby to save similar deaths. Hence, it is just and necessary that an interim compensation of Rs. 1000 Crores be granted to the Petitioner in the writ jurisdiction.

Moreover, this loss is not only to the Petitioner's family, but a loss to the whole dentistry community. Being an Oral Pathologist (MDS), she was

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GANGADHAR RAMJI VAIDYA
Advocate, Notary Govt. of India
Area- Aurangabad District
Mob No.9890093345
Reg No 15503

providing free services at various places in Nashik such as Santkrupa Hospital & Charitable Trust, NAMCO Hospital and many such places. She conducted free treatment for Thalessemia children at various camps held at Nashik. Being the most dynamic and enthusiastic teacher of SMBT college, she was most interested in research in dentistry. Proving this, she had encouraged and guided many of her students to present research papers at State level and National Level from SMBT college and made sure that they reach the Semi Final Round at 'Avishkaar'. Her contribution to the profession was numerous. She had been recently admitted to Ph. D at People's University Bhopal and was about to research on the topic was oral pathology and micro biology. Her dream which she had written in her bio-data clearly says that she wanted to promote research in dentistry in India and carry out research on cheaper treatment in Oral Cancer for the poor people coming from rural areas who cannot afford the heavy cost of treatment of Oral Cancer. Just because of the uninformed trial of vaccination made on her, she sacrificed her life for the country by participating in the trials of vaccination in the national movement of India. The petitioner seeks declaring the deceased a 'martyr' for she had sacrificed her precious life which could have made wonders in the field of dentistry in the future and would have guided many more such students saving lives of many poor people. Petitioner also seeks a dedicated research Institute to be started by the Government of India under the name of Dr. Snehal Lunawat where research in dentistry would be carried out in various areas.

Similarly, petitioner seeks compensation for the damages caused to the family due to fraudulent reply by SII even after they were very much knowing about the fact that such adverse events are cause of the vaccine. Their denial to the fact after learning the case study with the facts calls

BEFORE ME
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GANGADHAR RAMJI VAIDYA
Advocate, Notary Govt. of India
Area, Aurangabad District
Mob No.9850001343
Regd No 13503

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for fraud and offence punishable under I.P.C. for hiding the facts from us, denying help and non-co-operation at their part.

22.A The petitioner states that her daughter was working in Nasik and she took her vaccine on 28th January, 2021 at Nasik and she died hence, the present petition is filed before this Hon'ble Court and therefore, this Hon'ble Court has territorial jurisdiction to entertain, the present petition.

23. The Petitioner states that he has not filed any other petitions, pertaining to the subject matter of this Petition in this Hon'ble Court or in any other Court.

24. The Petitioner is approaching this Hon'ble Court expeditiously and there is no lapse and delay on his part.

25. The Petitioner has paid the prescribed court fees of Rs._____/-.

26. The Petitioner will rely upon the documents a list whereof is annexed hereto.

27. **PRAYERS:-**

The Petitioner therefore prays that, this Hon'ble Court may pleased to:

i) To hold that, the petitioner's daughter was given vaccine under deception, and false narratives by the state authorities that the vaccines are completely safe and if any serious or severe side effects occurs then the state authorities have define treatment, however when she suffered serious side effects then there was no treatment available and lastly she died due to side effects of vaccines as has been confirmed by the Government of India's AEFI Committee, therefore state authorities are responsible for causing her death by spreading false narratives and therefore, they are bound to compensate the petitioner in view of law laid by Hon'ble Supreme Court and Hon'ble High Courts and more particularly in the case of **Registrar General, High Court of Meghalaya Vs. State of Meghalaya 2021 SCC OnLine Megh 130**;

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GANGADHAR NAMJI VAIDYA
Advocate, Notary Govt. of India
Dist. Aurangabad District
Mob No.9890088503
Regd No 15503

ii) To hold that the respondent state authorities are having callous criminal attitude as till date they have not changed their frequently asked questions and even on **15.12.2021** they are continuing their false narratives that they are having definite treatment for any side effects of vaccines;

iii) To hold that as per law laid down by the Constitution Bench of Hon'ble Supreme Court in **Anita Khushwha's case (2016) 8 SCC 509**, the value of life of Indian citizen is not less than that of any person across the world either of America or of any country and therefore the Petitioner is entitled to the compensation in proportion to the compensation granted in other similar cases in United State, Singapore etc.

iv) To hold that, in view of factual and legal position mentioned in the petition, the petitioner is entitled for an interim compensation of Rs. 1000 Crores as a deterrence to guilty and as succor to petitioner's family for loss of life of petitioner's daughter due to deliberate act of commission and omission on the part of respondents, with a liberty to the state authorities to recover it from the responsible officials and **Serum Institute, Pune** who is the manufacturer of Covishield Vaccine, as per law & ratio laid down in **Veena Sippy Vs. Mr. Narayan Dumbre & Ors. 2012 SCC OnLine Bom 339;**

v) Direct appropriate action by the Respondent No. 3 Union of India against all including main stream and social media like Google, YouTube, facebook etc. who are involved in the conspiracy of

BEFORE ME
25/11/2021
SANGRAMSINH BAPU VAIDYA
Advocate, Notary, Govt. of India
Regd No 15503

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suppressing the correct data about death causing and other serious vaccine injuries and spreading false, misleading and one sided data to deprive the citizen to take informed decision and compel them to take vaccines;

vi) Direct the state authorities to take proper steps to stop further deaths of citizen and to publish the side effects of vaccines by following the rules of **Universal Declaration on Bioethics & Human Rights, 200** and as per law laid down in **Master Haridan Kumar Vs. UOI 2019 SCC online Del 11929** and also as recently done by the Government of Japan;

vii) Declare that, the Petitioner's daughter Dr. Snehal Lunawat and other doctors as a Martyr who were given Covid vaccines through deception and coercion and who died due to side effects of vaccines.

viii) Open a dedicated research institute in India under the name of Dr. Snehal Lunawat.

ix) Pass any other order which this Hon'ble Court may deems fit and proper in the fact and circumstances of the case.

Dated this 25th day of January, 2022

Petitioner

Advocate for the Petitioner

BEFORE ME
25/01/2022
GANGADHAR RAMJI VAIDYA
Advocate, Notary Govt. of India
Ahmedabad District
Regd No 15503

46-A

VERIFICATION

I, **Mr. Dilip Lunawat**, the petitioner do hereby on solemn affirmation state and declare that whatever stated above is true and correct to my own knowledge and belief and what is stated in abovesaid paragraphs is based on the information and legal advice which I believe to be true and correct.

Solemnly affirmed at Bombay)
This day of January, 2022)

BEFORE ME

Mr. Dilip Lunawat
(Petitioner)

Adv. Abhishek Mishra (I-23675)

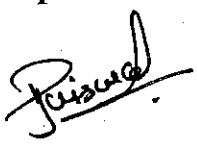
Advocate for Petitioner

Office No. 2 & 3, Kothari House,
5/7 Oak Lane, A R Allana Marg,
Near Burma Burma Restaurant,
Fort, Mumbai - 400 023.
adv.abhishekmishra1@gmail.com
Mob No.:- 9082530797.

AFFIDAVIT
Solemnly Affirmed Before Me
By Shri / Smt. Dilip Kisanlal Luna-wat
Age 66 Years Occu: service
R/o. Tapdiya Nagar
Who Identified By Abhishek Mishra Adv
Whom He/She is Personally Known
BEFORE ME
25/01/2022

ADV. GANGADHAR RAMJI VAIDYA
B.S.L., LL.B
Notary Govt. Of India
2,9/1, Tenali Nagar, 16th Scheme
N-2, CIDCO, Aurangabad
Mob No 9890089397

Adv. Deepika G. Jaiswal (I-30967)



Advocate for Petitioner

Office No. 2 & 3, Kothari House,

5/7 Oak Lane, A. R Allana Marg,

Near Burma Burma Restaurant,

Fort, Mumbai - 400 023.

adv.deepikajaiswal2201@gmail.com

Mob No.:- 8286370230.

India's Wait Over, Drug Regulator Says Covid Vaccines Cleared "110% Safe"

Source Name: NDTV

Link: https://www.ndtv.com/india-news/oxford-covid-19-vaccine-bharat-biotechs-covaxin-get-final-approval-by-drug-regulator-will-be-indias-first-vaccines-2347053

Date: January 04, 2021

Author Name: Anindita Sanyal.

Drug Controller General of India VG Somani said,."We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe".

New Delhi: Two vaccines for coronavirus, Oxford University's Covishield, which is being developed by the Pune-based Serum Institute, and Bharat Biotech's Covaxin, received emergency approval from the country's drug regulator on Sunday. "We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe," Drug Controller General of India VG Somani said, adding Covishield was found to be 70.42 per cent effective and Bharat Biotech's Covaxin was "safe and provides a robust immune response". Hailing the scientific community and frontline Corona warriors, Prime Minister Narendra Modi tweeted, "It would make every Indian proud that the two vaccines that have been given emergency use approval are made in India". There is no word yet on when the vaccination process will begin.

Here are the top 10 points in this big story:

1. "We'll never approve anything if there is slightest of safety concern. The vaccines are 110 per cent safe. Some side effects like mild fever, pain and

True Copy

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allergy are common for every vaccine," Drug Controller General of India VG Somani said. The approval from the Drug Controller comes days after a government-appointed experts' panel gave clearance to the vaccines.

2. Both vaccines have to be administered in two doses and stored at temperatures between 2 and 8 degrees Celsius. The government will give priority to 1 crore healthcare workers and 2 crore frontline workers when the vaccinations begin, Union Health Minister Dr Harshvardhan said as a countrywide dry run for the vaccination process was conducted on Saturday.

3. "It would make every Indian proud that the two vaccines that have been given emergency use approval are made in India! This shows the eagerness of our scientific community to fulfil the dream of an Aatmanirbhar Bharat, at the root of which is care and compassion," PM Modi tweeted.

4. Pune-based Serum Institute, the Drug Controller General said, conducted Phase 2 and Phase 3 trials on 1,600 participants in India. Recommendation was made for restricted use and the trials will continue, he added. The vaccine, developed by the Oxford University and pharma giant AstraZenca is already in use abroad.

5. Bharat Biotech's Covaxin is conducting trials in collaboration with the Indian Council of Medical Research. The Drug Controller said that its Phase I and Phase II trials were conducted in around 800 people and the results showed that it is "safe and provides a robust immune response". The Phase III trial in on and 22,500 of the 25,800 participants have been vaccinated.

6. The health ministry said the government's expert committee has reviewed Bharat Biotech's data on "safety and immunogenicity" and gave permission for "restricted use in emergency situation in public interest". The idea was to

have "more options for vaccinations, especially in case of infection by mutant strains," the ministry said, adding that the clinical trials will continue.

7. "Happy new year, everyone! All the risks @SerumInstIndia took with stockpiling the vaccine, have finally paid off. COVISHIELD, India's first COVID-19 vaccine is approved, safe, effective and ready to roll-out in the coming weeks," Serum Institute chief Adar Poonawalla tweeted.

8. "It has been learnt that the vaccines of Bharat Biotech and the Serum Institute have received emergency approval. All preparations are underway for the Delhi government. First health workers and frontline workers will be given the vaccine, Then those above age 50 will be given the vaccine. Health workers and frontline workers will be vaccinated under First phase," Delhi health minister Satyendar Jain said. The vaccines will be given free of cost in Delhi, the minister earlier said.

9. Flagging concerns over Bharat Biotech's Covaxin, senior Congress leader Shashi Tharoor tweeted, "The Covaxin has not yet had Phase 3 trials. Approval was premature and could be dangerous. @drharshvardhan should please clarify. Its use should be avoided till full trials are over. India can start with the AstraZeneca vaccine in the meantime".

10. India has reported 18,177 new infections in the last 24 hours - 4.7 per cent lower than yesterday - taking the total Coronavirus cases to 1,03,23,965. Data from the health ministry showed the country has also logged 217 deaths, taking the total number of fatalities to 1,49435.

EXHIBIT "B"

(50)

IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPLELATE JURISDICTION

PUBLIC INTEREST LITIGATIONNO.85 OF 2021

DISTRICT:

Yohan Tengra ... Petitioner

V/s

The State of Maharashtra & others ... Respondents

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3	2.	The copy of FAQ.	954-969

True Copy

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NOTARY
GOVT. OF INDIA

IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPLELATE JURISDICTION

PUBLIC INTEREST LITIGATION NO.85 OF 2021

DISTRICT:

YohanTengra ... Petitioner

V/S

1. The State of Maharashtra,
   Through Chief Secretary,
   State of Maharashtra,
   Mantralaya, Mumbai
2. Under Secretary,
   Disaster Management Unit,
   Mantralaya, Mumbai-23.
3. Shri. IqbalChahal,
   Municipal Commissioner,
   MCGM Annex Bldg. Fort, Mumbai-01.
4. Shri. ShirgangGholap,
   Under Secretary,
   Disaster Management Unit,
   Govt. of Maharashtra.
5. Shri. SitaramKunte,
   Chief Secretary, M.H State.
6. Ministry of Railways,

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Rail Bhawan, Rafi Marg, New Delhi.
7. The Union of India,
Through Chief Secretary,
To the Govt. of India, New Delhi-01.
8. Central Bureau of Investigaiton,
Lodhi Road, New Delhi-110003. ... Respondents

AFFIDAVIT IN REPLY

ON BEHALF OF RESPONDENT NO.

I,Dr.Sadhana M. Tayade, Age: 58, Service: presently working as Director of Health Services, Public Health Department, Mumbai, do hereby state on solemn affirmation on behalf of Respondent Nos. 1, 2, and 3 as under:-

1. I have read the copy of the present PIL along with the annexure thereto, also perused the official record pertaining to the subject matter of the case and on the basis of the information derived there from, I am filing this Affidavit-in-Reply to the above PIL. I am filing this Affidavit for the purpose of opposing the PIL. I say that the contentions, which are not specifically denied by me in this Affidavit-in-reply, should not be construed as an admission on my part. I crave leave of this Hon'ble Court to file additional affidavit, if so required. I am filing this affidavit as under:-

2. I say that present PIL has been filed by the Petitioner for directing the Respondent No.6to amend circular direction/Sop dt. 10.08.2021, 11.08.2021 and 15.07.2021 issued by the Respondent to the

extent by permitting non vaccinated people to travel by train and they should not be treated differently than those who are vaccinated and further prayed for directing the Respondents to open Local Trains for all irrespective of their status as vaccinated or non-vaccinated and also for other prayers mentioned in the said PIL.

3. I say that, the directions, circular/sop are issued by the State Government for the benefit of the public at large. I say that the said circular/sop are issued only after consulting with the various departments of the State Government more particularly the Task Force Committee constituted by the State. I further say that, the said circular are issued after consulting the Task Force Committee and after proper and detail study of the departments.

4. I say that the contention of the Petitioner in the present PIL is that, the vaccination is voluntary and not compulsory and the Petitioner has relied upon the various Judgments. I say that, in fact due to vaccinating the people the rates of hospitalization of COVID-19 patients is gradually reduced. Hereto annexed and marked as ***Exhibit-1*** is the copy of data showing reduction of hospitalization in COVID-19 patients.

5. I say that, thevaccination is important which could save the life. COVID-19 vaccines provide strong protection against serious illness hospitalization and death. There is also some evidence that being

951

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vaccinated will make it less likely that you will pass the virus on to others, which means your decision to get the vaccine also protects those around you.

6. I say that, the need for emergency care/hospitalization due to breakthrough COVID-19 is an exceedingly rate even in fully vaccinated patients. As vaccination has increased regionally, emergency care visits amongst fully vaccinated individuals have remained low and occur much less frequently than unvaccinated individuals. If, hospital-based treatment is required, elderly patients with significant comorbidities are at high-risk for severe outcomes regardless of vaccination status.Hereto annexed and marked as ***Exhibit-2*** is the copy of FAQ.

7. I further say and submit that, by not allowing the non-vaccinated people to open Local Trains or other public places is only to secure the right to live of the other vaccinated people.

In view of above appropriate order may be passed.

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VERIFICATION

I,Dr.Sadhana M. Tayade, Age: 58, Service: presently working as Director of Health Services, Public Health Department, Mumbai,do hereby state on solemn affirmation that whatever sated herein above is based upon the information derived from the official records, which I believe to be true and correct.

Solemnly affirmed at Mumbai.)

This day of December, 2021)

15/12/2021

(Dr.Sadhana M. Tayade)
Director of Health Services,
Public Health Department, Mumbai.

ID ..... 19/0389 by Govt of Mah.
Seen Org. / PAN Card No. .....

I identify the **Deponent,**

BEFORE ME

MANISH M. PABALE
B.A., LL.M.,
ADVOCATE & NOTARY (GOVT. OF INDIA)
104, Natwar Chambers,
94 Nagindas Master Road,
Fort, Mumbai - 400 001.

Clerk to the
Office of the Government Pleader,
A.S. (Writ Cell), High Court, Mumbai.

Drafted :-

NOTED & REGISTERED
Page No. 44/02 Sr. No. 808
Date 15 DEC 2021

Mrs.R. A. Salukhe
Assistant Government Pleader,
A.S. (Writ Cell), High Court, Mumbai.

Settled by:-

Mr. P. P.Kakade
Government Pleader,
A.S. (Writ Cell), High Court, Mumbai

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EXH-1

953.

No. of Admitted patient information and Covid 19 vaccination performance							
Sr. No.	On Date	No. of Admitted patient	Eligible Target Population for vaccination	1st dose Performance	%	2nd dose Performance	%
1	5/31/2021	97853	91435000	18009903	19.70	4570306	5.00
2	6/30/2021	38018	91435000	26070687	28.51	6373224	6.97
3	7/31/2021	33163	91435000	33384721	36.51	11202851	12.25
4	8/31/2021	16818	91435000	43090513	47.13	16002636	17.50
5	9/30/2021	10134	91435000	57644999	63.04	24267887	26.54
6	10/31/2021	4311	91435000	67201631	73.50	30976476	33.88
7	11/30/2021	2775	91435000	74334513	81.30	40045655	43.80
8	12/13/2021	2466	91435000	77916475	85.22	46621812	50.99

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Exh-2

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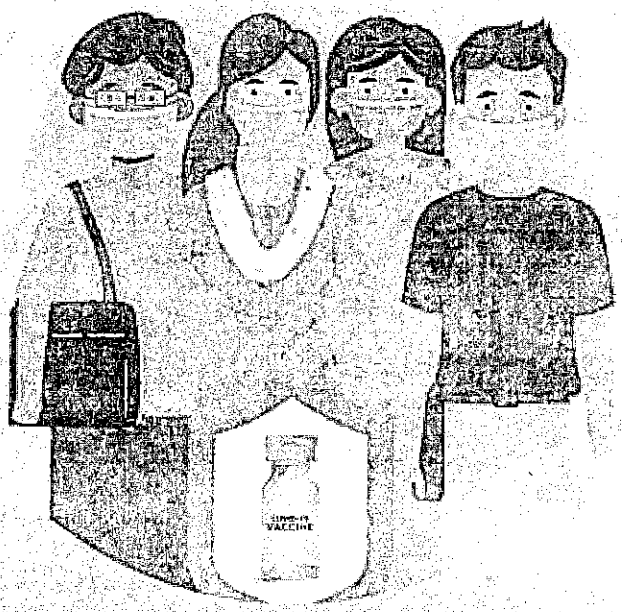
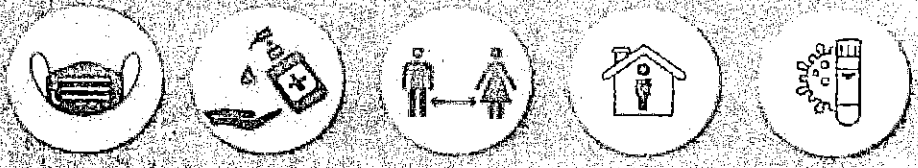


COVID-19 Vaccination FAQs for 18-44 YEAR AGE GROUP



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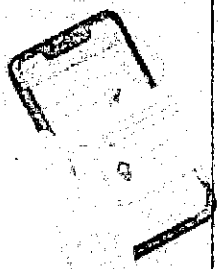
1 **From when the COVID-19 vaccination for 18-44 year age group is starting?**

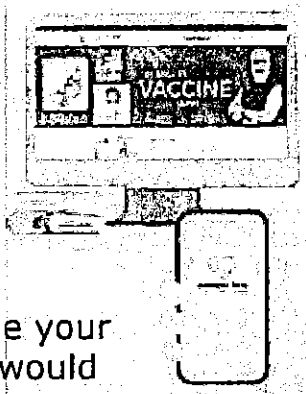


Registrations have started on 28 April and vaccination has started on 01 May. Please check www.cowin.gov.in for available slots and vaccination centres.

2 **Where can I get the Vaccine from?**

You can get the vaccine from Govt Hospital in districts which are selected by State Govt.
You can also get vaccine in selected private hospital vaccination centers. Check cowin.gov.in for details after registration.

3 **How to register for Vaccination?**



Registration is only via CoWIN Website (www.cowin.gov.in)/Aarogya Setu App only. No other app/website/walk-in/spot registration would be allowed.
Register using mobile number and Aadhaar number. Follow the simple steps as guided by the website, register, and choose your Vaccination Centre via Pin code/District. You would get an SMS Confirmation. Keep it safe.

4 **Can a person get the COVID-19 vaccine without registration with Health Department?**

No, the registration of beneficiary is mandatory for vaccination for COVID-19 vaccine.

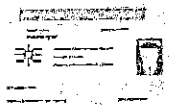
5 **After registration; the beneficiaries have to book a slot for vaccination or walk into the vaccination center**

For 18 to 44 age group vaccination no walk in is permitted as of now. Vaccination in this age group will only possible through scheduled appointment. Appointment can be sought on cowin.gov.in after registration. Notification and information about the vaccine session date and time will be shared with the beneficiary after scheduling the appointment.

6 What documents are required for registration of eligible beneficiary?

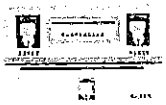
Any of the below mentioned ID with Photo may be produced at the time of registration:

Aadhaar Card


Driving License

Health Insurance Smart Card issued under the scheme of Ministry of Labour

Mahatma Gandhi National Rural Employment Guarantee Act (MGNREGA) Job Card

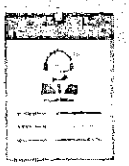

Official identity cards issued to MPs/MLAs/MLCs

PAN Card

Passbooks issued by Bank/Post Office

Passport

Pension Document


Service Identity Card issued to employees by Central/ State Govt./ Public Limited Companies

Voter ID

7 Can I reschedule my Vaccination Appointment?

Yes. You can reschedule till the previous day.

8 What are the vaccines that would be made available?

At present, COVISHIELD (Oxford-AstraZeneca Vaccine) and COVAXIN (Bharat Biotech) would be available. In due course, many other vaccines are expected to be made available.
While booking the appointment, you will be able to see both the name of the centre and the vaccine being given in private facility. Vaccine of choice among the available options at the displayed cost may be received from private facilities. At Government facilities/ sites there is no choice of vaccine.

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9 **How much should I pay for the vaccine dose?**

In the private sector, the price would be decided by the Private Vaccine Providers.
In the government hospitals, the vaccine will be available free of cost in Uttar Pradesh.

10 **I am a young person. Is COVID-19 vaccines (COVISHIELD and COVAXINE) are safe?**

Yes, Both the available vaccines are entirely safe and effective. Millions of persons have received COVISHIELD and COVAXINE in India, with extremely rare side effects. And, even in the unlikeliest scenario of a serious adverse event, there are established management protocols. There is nothing to fear.

11 **Can a pregnant or lactating woman receive COVID-19 vaccine?**

Studies are ongoing to prove the safety of COVID-19 vaccines in pregnant and lactating women. Currently, Government of India guidance does not include vaccination for pregnant and lactating women.

12 **I am on my periods. Can I receive the vaccine?**

Yes, you can. Kindly do not believe the rumours regarding the same.

13 **Which of the vaccines is better for me - COVISHIELD or COVAXIN?**

Both are equally efficacious in preventing mild, moderate, and severe COVID. Choose whatever is available to you, at the Vaccination Centre.

14 **I am young. I believe I have good immunity. Do I need to still take the Vaccine?**

Yes. No one is safe from COVID-19, not even the fittest and healthiest of individuals. Better safe, than sorry.

15 **I am hearing reports of people testing COVID-19 Positive even after receiving the first dose of Vaccine. Is it even useful?**

First, the rate of infection after vaccination is much lower than the unvaccinated. And, even if such an infection occurs, by virtue of the vaccination, the body has a good titre of antibodies to limit the infection to a mild stage, thereby significantly reducing the chance of progressing to severe COVID, hospitalization and deaths. Therefore, vaccines are life-saving and effective!

16 **What are the common side effects that I can expect after Vaccination?**

Fever, headaches, body aches, fatigue, injection site pain are the common side effects, and they are manageable by a short course of Paracetamol. Most resolve by 2-3 days. You are observed for 30 minutes after receiving the dose, for any serious or severe effects, and even though they are rare to occur, there is definite treatment for each such serious effect.

17 **I recently tested COVID-19 Positive. Should I still take the vaccine?**

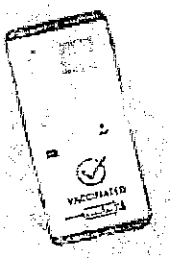
Yes. You should receive the vaccine 4-8 weeks after testing COVID-19 positive.

18 **I received the First Dose of the Vaccine and then tested COVID-19 Positive in between the two doses? Can I take the second dose?**

Yes. You should receive the vaccine 4-8 weeks after testing COVID-19 positive.

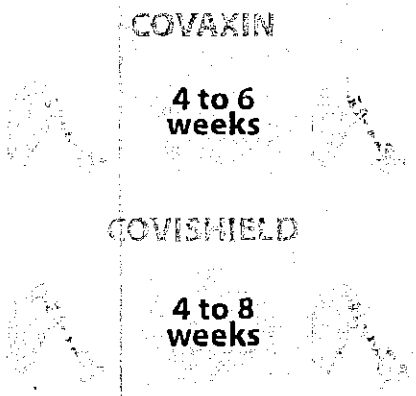
959

19 **Will vaccinated beneficiaries receive information on the status of their vaccination after completion?**



Yes. On getting due dose of COVID-19 vaccine, the beneficiary will receive SMS on their registered mobile number. After all doses of vaccine are administered, a QR code-based certificate will also be sent to the registered mobile number of the beneficiary.

20 **What is the dose schedule of both the vaccines?**



The second dose of Covishield vaccine can be taken 4-8 weeks after the first dose and the second dose of Covaxin can be taken 4-6 weeks after the first dose.

21 **Is it mandatory to take the vaccine?**

Vaccination for COVID-19 is voluntary. However, it is advisable to receive the complete schedule of COVID-19 vaccine for protecting oneself against this disease and to limit the spread of this disease to the close contacts including family members, friends, relatives, and co-workers.

22 **If one is taking medicines for illnesses like Cancer, Diabetes, Hypertension etc, can s/he take the COVID-19 vaccine and/or If I suffer from HTN/DM/ CKD/heart disease/lipid disorders etc., can I safely take this vaccine?**

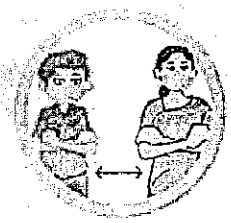
Yes, persons with one or more of these comorbid conditions are considered among the high-risk categories. They need to get COVID-19 vaccination on priority. Overall, the vaccine is safe and efficacious in adults with comorbidity. The maximum benefit of getting the COVID-19 vaccine is for those who have such co-morbidities. However, if you are concerned for any specific reason, please consult your doctor

23 **Do I need to use the mask/other COVID-19 appropriate precautions after receiving the vaccine?**

Yes, it is absolutely necessary that everyone who has received the COVID-19 vaccine should continue to follow the COVID-19 appropriate behaviour i.e., mask, do gaj ki doori and hand sanitization to protect themselves and those around from spreading the infection.

Use mask correctly

Wash hands with soap and water frequently and thoroughly or use hand sanitizer



Maintain 6 feet (2 gaj) physical distance

24 **How long will I remain protected after vaccination?**

Longevity of the immune response in vaccinated individuals is yet to be determined. Hence, continuing the use of masks, handwashing, physical distancing, and other COVID-19 appropriate behaviours is strongly recommended.

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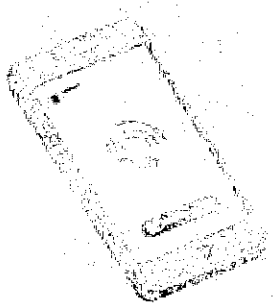
25 **Does vaccination protect me against newer strains / mutated virus of SARS-CoV 2?**

The body responds to vaccination by making more than one type of antibodies to virus parts including spike protein. Therefore, all vaccines are expected to provide reasonable amount of protection against the mutated virus also. Based on the available data the mutations as reported are unlikely to make the vaccine ineffective.

26 **In how many days will the vaccination create an adequate immune response and protection?**

Adequate immune response takes 2-3 weeks after completion of entire vaccination schedule i.e., after the second dose of COVISHIELD® and COVAXIN®.

27 **What precautions do I need to take after receiving the vaccine?**



Both the vaccines are safe, but in case of any discomfort or complaint, ask the beneficiary to visit the nearest health facility and/or call the health worker whose phone number is given in the Co-WIN SMS received after vaccination.

28 **Is it important for me to receive the same vaccine during second dose?**

As the vaccines available are not inter-changeable, it is important to receive the second dose of the same vaccine as the first one. The Co-WIN portal is also going to help to ensure that everyone receives the same vaccine

True Copy

EXHIBIT" C "

Ministry of Health & Family Welfare
Government of India

Certificate for COVID-19 Vaccination

Issued in India by Ministry of Health & Family Welfare, Govt. of India

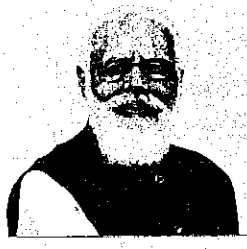
Certificate ID 285136017

Beneficiary Details

Beneficiary Name / लाभार्थीचे नाव	**Dr.Snehal Dilip Lunawat**
Age / वय	**33**
Gender / लिंग	**Female**
ID Verified / ओळखपत्र	**PAN Card # AHOPL8160H**
Unique Health ID (UHID)	
Beneficiary Reference ID	**21389753155348**
Vaccination Status / लसीकरण स्थिती	**Partially Vaccinated (1 Dose)**

Vaccination Details

Vaccine Name / लसीचे नाव	**COVISHIELD**
Vaccine Type / लस प्रकार	**COVID-19 vaccine, non-replicating viral vector**
Manufacturer / उत्पादक	**Serum Institute of India**
Dose Number / डोस क्रमांक	**1/2**
Date of Dose / डोसची तारीख	**28 Jan 2021**
Batch Number / बॅच क्रमांक	**4120Z012**
Next Due Date / पुढील देय तारीख	**Between 22 Apr 2021 and 20 May 2021**
Vaccinated By / यांच्याद्वारे लसीकरण	**Sunil Shinde**
Vaccination At / लसीकरणाचे स्थळ	**SMBT Medical collage, Nashik, Maharashtra**



औषध सुद्धा आणि शिस्त सुद्धा
Together, India will defeat COVID-19"
- पंतप्रधान श्री. नरेंद्र मोदी

In case of any adverse events, kindly contact the nearest Public Health Center/ Healthcare Worker/District Immunization Officer/State **Helpline No. 1075**

कोणतेही प्रतिकूल परिणाम आढळून आल्यास कृपया जवळचे सार्वजनिक आरोग्य केंद्र/ आरोग्यसेवा कर्मचारी/ जिल्हा लसीकरण अधिकारी/ राज्य हेल्पलाइन क्रमांक १०७५ वर संपर्क साधा.

COWIN
Winning Over COVID

True Copy

This certificate can be verified by scanning the QR code at http://verify.cowin.gov.in

EXHIBIT "D" (66)

Z.16025/02/2018-IMM-Part(1)
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Date: 02nd October 2021

Causality assessment result of one reported Serious Adverse Events Following Immunization (AEFI) case following COVID-19 vaccination approved by National AEFI Committee on 25th September 2021.

The Immunization Division, MOHFW has taken several steps to strengthen the national AEFI surveillance system for COVID-19 vaccinations. Considering the importance and critical nature of the task, steps were taken to include medical specialists, cardiologists, neurologists, pulmonary medicine specialists, obstetrician-gynecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct causality assessment of AEFIs following COVID-19 vaccination. The result of causality assessment done by this Special Group is discussed in the National AEFI committee meeting for final approval.

The result of the causality assessment of one case completed on 25th September 2021 after thorough review, deliberation and approval by the National AEFI Committee is given in the annexure (anonymized line list of the causality assessment done by the National AEFI Committee).

This death case for which Causality assessment has been done was found to have **consistent causal association to vaccination.**

Vaccine product related reactions are expected reactions that can be attributed to vaccination based on current scientific evidence. Examples of such reactions are allergic reactions and anaphylaxis, etc.

Indeterminate reactions are reactions which have occurred soon after vaccination but there is no definitive evidence in current literature or clinical trial data that this event could have been caused due to the vaccine. Further observations, analysis and studies are required.

Unclassifiable events are events which have been investigated but there is not enough evidence for assigning a diagnosis due to missing crucial information. When this relevant information becomes available, the case may be reconsidered for causality assessment.

Coincidental events are events that are reported following immunization but for which a clear cause other than vaccination is found on investigation.

Overall, the benefits of vaccination are overwhelmingly greater than the small risk of harm. However, as a measure of utmost precaution, all emerging signals of harm are being constantly tracked and reviewed periodically.

True Copy

CAUSALITY CLASSIFICATION OF one AEFI CASE APPROVED BY THE NATIONAL AEFI COMMITTEE ON 25 SEP 2021- (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION

C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(s), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE

D - UNCLASSIFIABLE

SL NO	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION BY NATIONAL AEFI COMMITTEE	STATUS OF APPROVAL BY NATIONAL AEFI COMMITTEE
1	IND(CO-AEFI)MHNSK21001	2021	34	FEMALE	DEATH	28-01-2021	COVISHIELD	Right transverse sinus thrombosis with right temporal haemorrhagic infarct, right posterior frontal haemorrhagic infarct with thrombocytopaenia	A1	25-09-2021

*Covid vaccine is a new vaccine. The causality may change as more information become available.

Verified by Dr Anju Seth on 26th September 2021

EXHIBIT "E" (68)

05/10/2021

रजिस्टर्ड डाक
REGISTERED POST

By Registered Post

BEFORE THE FIRST APPELLATE AUTHORITY UNDER SECTION 19(1) OF THE RTI ACT 2005

In the matter of RTI Appeal Registration No. MOHFW/A/E/21/00692 dated 06.09.2021 filed by Ms. Sapna Dilip Lunawat, D-3, Tirupati Garden, Tapadiya Nagar, Darga Road, Aurangabad, Maharashtra – 431005 (hereinafter referred as 'the Appellant')

ORDER

In the RTI Request Registration No. MOHFW/R/T/21/01430 dated 12.05.2021, information on seven points was sought under the RTI Act, 2005.

2. It is seen from the records that the CPIO of Immunisation Section already provided a reply through RTI Portal on 14.07.2021 as under:

Information sought	Reply given
1) Details of all the cases of specific embolic and thrombotic events in combination with low levels of blood platelets (thrombocytopenia) found in the patients all over India reported with you post Covishield vaccination. Details should contain Name, Age, Gender, Place, Hospital name.	The information sought does not pertain to Immunization Division and, hence, there is no information to furnish.
2) Details of all Adverse Events / impairment (temporary or permanent disability) due to cerebral venous sinus thrombosis post Covishield vaccination and have survived. Details should contain Name, Age, Gender, Address and Contact details, Hospital name, disability in which part of the body.	
3) Details of death events other than above ocurred post Covishield vaccination and survived. Details should contain Name, Age, Gender, Place and Hospital name, reason of death.	The information sought is available at http://main.mohfw.gov.in/Organisation/Departments-of-Health-and-Family-Welfare/immunization/aefi-reports
4) Details of Adverse Events / impairment (temporary or permanent disability) occurred in patients post Covishield vaccination and have survived. Details should contain Name, Age, Gender, Place, Hospital name, disability in which part of the body.	

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(69)

5) Investigation reports of the investigations done by the government officials, Health Ministry and Serum Institute of India in the cases specified in Point Numbers 1 to 4.	
6) Provide number of deaths occurred in India from 15th January, 2021 toll 30th April, 2021 with a bifurcation between vaccinated (Covisield and Covaxin) deaths and non-vaccinated deaths. Graphical representation with numbers as well.	
7) Detailed analysis and report of the investigation done by you on the death of a 32 years old doctor from Nashik. Maharashtra, Dr. Snehal Lunawat case, as published in The Economics Times dated 29.04.2021 and Times of India dated 23.04.2021 wherein the government officials have said that they have investigated the case and have not found anything unusual and there was no major concern found in this case. (i) Investigation reports of the case given by Government Officials. (ii) Basis of your conclusions in the above case. (iii) Date-wise procedure carried out by you to perform investigation of the above case. (iv) Whether the advisory on cases of adverse events have been issued by the government. If so, copy of the same.	The information sought does not pertain to Immunization Division and, hence, there is no information to furnish.

3. Subsequently, the Appellant has filed aforesaid Appeal on the ground *"Refused Access to Information Requested"*. It is also stated that the information sought is not of public interest and it is regarding her own sister and she is eligible to get the same.

4. After receipt of aforesaid Appeal, the First Appellate Authority has made an effort to ascertain whether specific / additional information is available with the CPIO of Immunization Section and whether other CPIO(s) were also involved in providing information in response to the RTI Request. In this regard, the CPIO of Immunisation Section has informed that the information has been sought from concerned Department for providing inputs and the Immunization Section has received information concerned Department. Thus, point-wise information in response to the RTI Request dated 12.05.2021 is provided as **Annexure**.

5. In the light of above, the appeal of the Appellant under Section 19(1) of the RTI Act, 2005 has been treated as disposed of.

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6. If the Appellant is not satisfied with this Order, an appeal may be filed to the Second Appellate Authority, Central Information Commission, CIC Bhawan, Baba Gangnath Marg, Munirka, New Delhi – 110067 within 90 days from the date of receipt of this Order.

Encl. As above.

(Elangbam Robert Singh)
Director (RCH) & First Appellate Authority
Ministry of Health and Family Welfare
Room No.405, 'D' Wing, Nirman Bhawan
Maulana Azad Marg, New Delhi – 110011
Tel # 011-23062495

F.No. Z.33013/238/2021-IMM Dated 05th October, 2021

Ms. Sapna Dilip Lunawat,
D-3, Tirupati Garden,
Tapadiya Nagar, Darga Road,
Aurangabad, Maharashtra – 431005
(Email: sapnalunawat@gmail.com)

3.55 PM

(71)

Annexure

Information in response to RTI Appeal Registration No. MOHFW/A/E/21/00586 dated 06.08.2021 filed by Ms. Sapna Dilip Lunawat

Point 1: Details of all the Cases of specific embolic and thrombotic events in combination with low levels of blood platelets (thrombocytopenia) found in the patients all over India reported with you post Covishield vaccination. Details should contain Name, Age, Gender, Place, Hospital name.

Information: Two suspected cases of embolic and thrombotic events in combination with low levels of blood platelets (thrombocytopenia) following Covishield vaccination were identified in 498 cases rapidly reviewed and assessed by medical experts. Both these cases were in females above 50 years of age. Personal details of the reported cases are not shared under Section 8(1)(j) of the RTI Act, 2005.

Point 2: Details of all Adverse events/impairment (temporary or permanent disability) due to cerebral venous sinus thrombosis post Covishield vaccination and have survived. Details should contain Name, Age, Gender, Address and Contact details, Hospital name, disability in which part of the body.

Information: Only one case of suspected cerebral venous sinus thrombosis following Covishield vaccination has been reported in 498 cases assessed by the medical experts. This case has recovered and has been discharged. The reported case was of 32 years old female. Personal details of the reported case are not shared under Section 8(1)(j) of the RTI Act, 2005.

Point 3: Details of death events other than above occurred post Covishield vaccination. Details should contain Name, Age, Gender, Place, Hospital name, reason of death.

Information: As on 30th September 2021, a total of 78,70,57,398 doses of Covishield vaccine had been administered in the country and 710 death cases were reported (reporting rate of 1.1 case per million doses of Covishield vaccine administered). It may be noted that mere reporting of an event does not imply causality. Only a detailed investigation and causality assessment by the trained medical experts can ascertain the causal relationship of the event and the vaccine. Out of 710 death cases, 438 cases were reported in males and 272 cases in females. There were 113, 208 and 389 deaths in age group of <45 years, 45 years-60 years, >60 years age groups respectively. Personal details of the reported cases are not shared under Section 8(1)(j) of the RTI Act, 2005. Causality assessment details may be seen at the following link:
https://main.mohfw.gov.in/Organisation/Departments-of-Health-and-Family-Welfare/immunization/aefi-reports

Point 4: Details of Adverse events/impairment (temporary or permanent disability) occurred inpatients post Covishield vaccination other than those mentioned above and have survived. Details should contain Name, Age, Gender, Place, Hospital name, and disability in which part of the body.

Information: As on 30th September 2021, a total of 78,70,57,398 doses of Covishield vaccine had been administered in the country and 1765 serious/severe cases were reported (reporting rate of 2.7 case per million doses of Covishield vaccine administered). It may be noted that mere reporting of an event does not imply causality. Only a detailed investigation and causality assessment by the trained medical experts can ascertain the causal relationship of the event and the vaccine. Personal details of the reported cases are not shared under Section 8(1)(j) of the RTI Act, 2005. Causality assessment details may be seen at the following link: https://main.mohfw.gov.in/Organisation/Departments-of-Health-and-Family-Welfare/immunization/aefi-reports

Point No 5: Investigation reports of the investigations done by the government officials, Health Ministry and Serum Institute of India in the cases specified in point numbers 1 to 4.

Information: As per COVID-19 operational guideline, all suspected serious/ severe AEFI cases reported are to be investigated by the District AEFI committee in the prescribed Case Reporting Form (CRF) and the Case Investigation Form (CIF) within the defined time frame. Once all the relevant case forms along with the supporting documents such as hospital records, post mortem/verbal autopsy (in death cases) are received by the State and national AEFI committees, these cases are assessed for causality by the trained medical experts. The investigation reports for the reported serious/severe cases are not shared under Section 8(1)(j) of the RTI Act, 2005. For investigation reports, if any done by Serum Institute of India (SII) may be asked by the RTI Appellant directly from SII.

The reporting and investigations of AEFIs are the function of the District Immunization Officer (DIO) and the District AEFI committee. Since the forms are filled by the DIO, the Appellant may approach the District/State authorities to share the investigation reports with the Appellant *[According to the guidelines given at Para 3(iv) of D/o Personal & Training, Government of India's O.M. No. 10/2/2008-IR dated 12.06.2008 (copy enclosed as **Enclosure-1**), if a person makes an application to a public authority for some information which is the concern of a public authority under any State Government or Union Territory Administration, the Central Public Information Officer (CPIO) of the public authority receiving the application should inform the applicant that the information may be had from the concerned State Government / UT Administration and the application, in such case, need not be transferred to the State Government / UT Administration. Thus, the Appellant may obtain the information from the State Government / UT Administration concerned as the same will be available with the authorities of the State / UT concerned].*

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Point No 6: Provide number of deaths occurred in India from 15th January, 2021 till 30th April, 2021 with a bifurcation between vaccinated (Covishield and Covaxin) deaths and non-vaccinated deaths. Graphical representation with numbers as well.

Information: Total number of COVID-19 vaccine administered from 16th January, 2021 till 30th April, 2021 is 15,49,89,635. A total of 412 suspected AEFI deaths were reported post COVID- 19 vaccination (reporting rate of 2.7 death case per million COVID-19 vaccine doses). Of these 412 deaths, there were 396 deaths following Covishield (0.28 death case per one lakh doses) and 16 deaths following Covaxin (0.11 deaths per one lakh doses). Information on the number of deaths in non-vaccinated population is not available with Immunization Division of the Ministry of Health & Family Welfare.

Point No 7: Detailed analysis and report of the investigation done by you on the death of a 32 years old doctor from Nashik, Maharashtra, Dr. Snehal Lunawat case, as published in The Economics Times dated 29.04.2021 and Times of India dated 23.04.2021 wherein the government officials have said that they have investigated the case and have not found anything unusual and there was no major concern found in this case.

(i) Investigation reports of the case given by Government Officials.

Information: As per COVID-19 operational guideline, the case reporting form (CRF) and the Case Investigation Form (CIF) along with the relevant case records (hospital recordsor post-mortem report or verbal autopsy report in case of death cases) for all suspected serious/severe AEFI cases are to be filled/collected and submitted by the District Immunization Officer to the District AEFI committee. These are also uploaded on the CoWIN portal. Since investigation is the function of the DIO and District AEFI committee, the Appellant may approach the District authorities to share the investigation reports of the case with the Appellant *[According to the guidelines given at Para 3(iv) of D/o Personal & Training, Government of India's O.M. No. 10/2/2008-IR dated 12.06.2008 (copy enclosed as Enclosure-1), if a person makes an application to a public authority for some information which is the concern of a public authority under any State Government or Union Territory Administration, the Central Public Information Officer (CPIO) of the public authority receiving the application should inform the applicant that the information may be had from the concerned State Government / UT Administration and the application, in such case, need not be transferred to the State Government / UT Administration. Thus, the Appellant may obtain the information from the State Government concerned as the same will be available with the authorities of the State concerned].* After receipt of investigation reports from the State/UT, the causality assessment done at National level and as approved by the National AEFI committee that AEFI death belongs to A1 category meaning by that it is related to vaccine product related reaction.

(ii) Basis of your conclusions in the above case.

Information: The case records for the above-mentioned case has been reviewed by the National AEFI Committee. The causality assessment of the case is completed and approved by the National AEFI Committee, the results will be shared with the State Government as well as with CDSCO (Central Drugs Standard Control Organization).

(iii) Date-wise procedure carried out by you to perform investigation of the above case.

Information: The investigation reports and case documents (hospital records, etc.) have been received on 8th June 2021 at the national level through CoWIN. These were screenedon 29th June 2021 as well as put up for causality assessment meeting held online on 17th September 2021 and on 25th September 2021 the National AEFI Committee reviewed and approved the case.

(iv) Whether the advisory on cases of adverse events have been issued by the government? If so, copy of the same.

Information: An advisory for doctors on recognizing, managing and reporting Thrombosis and Thrombocytopenia Syndrome cases and an advisory for vaccinators to inform vaccine beneficiaries on reporting such cases to the vaccinator or DIO have been issued by the Government. Details of the advisory in the Press Release are in the link below: https://www.pib.gov.in/PressReleseDetailm.aspx?PRID=1719293 - Bleeding and clotting events following COVID vaccination miniscule in India - National AEFI (Adverse Event Following Immunization) Committee submits report to the Union Health Ministry - Posted On: 17th May, 2021 at 2:32 PM by PIB Delhi.

Copies of the advisories to strengthen the AEFI surveillance and official letters issued to States/UTs on the same are also enclosed as **Enclosure-2.**

(75)

Enclosure - 1

4

2068056/2021/MATERNAL HEALTH

No.10/2/2008-IR
Government of India
Ministry of Personnel, Public Grievances & Pensions
Department of Personnel & Training

North Block, New Delhi
Dated: the 12th June, 2008

OFFICE MEMORANDUM

Subject: RTI applications received by a public authority regarding information concerning other public authority/authorities.

*****

It has been brought to the notice of this Department that requests are made to the public authorities under the Right to Information Act for pieces of information which do not concern those public authorities. Some times, such an information is sought, a part or no part of which is available with the public authority to which the application is made and remaining or whole of the information concerns another public authority or many other public authorities. A question has arisen as to how to deal with such cases.

2. Section 6(1) of the RTI Act, 2005 provides that a person who desires to obtain any information shall make a request to the public information officer (PIO) of the concerned public authority. Section 6(3) provides that where an application is made to a public authority requesting for any information which is held by another public authority or the subject matter of which is more closely connected with the functions of another public authority, the public authority to which such application is made, shall transfer the application to that other public authority. A careful reading of the provisions of sub-section (1) and sub-section(3) of Section 6, suggests that the Act requires an information seeker to address the application to the PIO of the 'concerned public authority'. However, there may be cases in which a person of ordinary prudence may believe that the piece of information sought by him/her would be available with the public authority to which he/she has addressed the application, but is actually held by some another public authority. In such cases, the applicant makes a bonafide mistake of addressing the application to the PIO of a wrong public authority. On the other hand where an applicant addresses the application to the PIO of a public authority, which to a person of ordinary prudence, would not appear to be the concern of that public authority, the applicant does not fulfill his responsibility of addressing the application to the 'concerned public authority'.

...2/-

3. Given hereinunder are some situations which may arise in the matter and action required to be taken by the public authorities in such cases:

(i) A person makes an application to a public authority for some information which concerns some another public authority. In such a case, the PIO receiving the application should transfer the application to the concerned public authority under intimation to the applicant. However, if the PIO of the public authority is not able to find out as to which public authority is concerned with the information even after making reasonable efforts to find out the concerned public authority, he should inform the applicant that the information is not available with that public authority and that he is not aware of the particulars of the concerned public authority to which the application could be transferred. It would, however, be the responsibility of the PIO, if an appeal is made against his decision, to establish that he made reasonable efforts to find out the particulars of the concerned public authority.

(ii) A person makes an application to a public authority for information, only a part of which is available with that public authority and a part of the information concerns some 'another public authority.' In such a case, the PIO should supply the information available with him and a copy of the application should be sent to that another public authority under intimation to the applicant.

(iii) A person makes an application to a public authority for information, a part of which is available with that public authority and the rest of the information is scattered with more than one other public authorities. In such a case, the PIO of the public authority receiving the application should give information relating to it and advise the applicant to make separate applications to the concerned public authorities for obtaining information from them. If no part of the information sought, is available with it but is scattered with more than one other public authorities, the PIO should inform the applicant that information is not available with the public authority and that the applicant should make separate applications to the concerned public authorities for obtaining information from them. It may be noted that the Act requires the supply of such information only which already exists and is held by the public authority or held under the control of the public authority. It is beyond the scope of the Act for a public authority to create information. Collection of information, parts of which are available with different public authorities, would amount to creation of information which a public authority under the Act is not required to do. At the same time, since the information is not related to any one particular public authority, it is not the case where application should be transferred under sub-section (3) of Section 6 of the Act. It is pertinent to note that sub-section (3) refers to 'another public authority' and not 'other public authorities'. Use of singular form in the Act in this regard is important to note.

....3/-

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2068056/2021/MATERNAL HEALTH

(iv) If a person makes an application to a public authority for some information which is the concern of a public authority under any State Government or the Union Territory Administration, the Central Public Information Officer (CPIO) of the public authority receiving the application should inform the applicant that the information may be had from the concerned State Government/UT Administration. Application, in such a case, need not be transferred to the State Government/UT Administration.

4. Contents of this OM may be brought to the notice of all concerned.

(K.G. Verma)
Director

1. All the Ministries / Departments of the Government of India
2. Union Public Service Commission/ Lok Sabha Sectt./ Rajya Sabha Secretariat/ Cabinet Secretariat/ Central Vigilance Commission/ President's Secretariat/ Vice-President's Secretariat/ Prime Minister's Office/ Planning Commission/Election Commission.
3. Central Information Commission/State Information Commissions.
4. Staff Selection Commission, CGO Complex, New Delhi
5. Office of the Comptroller & Auditor General of India, 10, Bahadur Shah Zafar Marg, New Delhi.
6. All officers/Desks/Sections, Department of Personnel & Training and Department of Pension & Pensioners Welfare.

Copy to: Chief Secretaries of all the States/UTs.

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Enclosure-2

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi - 110011

Dr. Manohar Agnani, IAS
Additional Secretary
Tele: 011-23061723
e-mail: jsrch-mohfw@gov.in

D. No: T.13020/08/2018-IMM
Date -18th November 2020

Dear All,

You may be aware that preparations are underway for conducting COVID19 vaccinations in states and districts, starting with certain priority groups. In connection with this, steps need to be taken to strengthen Adverse Events Following Immunization (AEFI) surveillance following COVID19 vaccinations to maintain confidence in safety of vaccines. MoHFW has identified initiatives which are essential to further strengthen the existing AEFI Surveillance System of India so that timely & complete AEFI reporting for COVID19 vaccination is possible. These initiatives are enclosed with this letter.

I request that these initiatives are implemented at the earliest so that required changes take place well before the COVID19 vaccine is introduced in the district/state. For any additional information or support in implementing the above interventions. State/UT may contact the Senior Zonal AEFI Consultant of your state or your local Surveillance Medical Officer, WHO-NPSP or the AEFI Secretariat, MoHFW.

With kind regards,

Yours sincerely,

18/11/2020

(Dr. Manohar Agnani)

Additional Chief Secretary/Principal Secretary/Secretary (Health), all states/UTs

Copy to:

1. Mission Director (NHM), all states/UTs
2. Chair, National AEFI Committee
3. Chairpersons of State AEFI Committees
4. Dr Jaiprakash, Secretary-cum-Scientific Advisor (I/C), Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Govt. of India, Sector-23, Raj Nagar, Ghaziabad-201 002.
5. State Immunization Officer, all states/UTs
6. Dr Pankaj Bhatnagar, Acting Team Lead, WHO-NPSP
7. Dr Vineet Goyal, AEFI Focal Person, WHO-NPSP
8. Team Lead – AEFI, ITSU

Annexure

Initiatives to Strengthen AEFI Surveillance System for COVID19 Vaccination

1. **Include medical specialists in addition to paediatricians in state and district AEFI committees** - The COVID19 vaccinations will be given to adults, many of whom may have co-morbidities. Events due to pre-existing comorbidities (strokes, heart attacks, etc.) may be reported as AEFIs following COVID19 vaccinations. Membership of State AEFI Committees should be revised to include neurologists, cardiologists, respiratory medicine specialists who can recognise such events and differentiate them from events related to vaccines/ vaccinations. Similarly, directions may be issued to districts to include medical specialists (neurologists, cardiologists) in the district AEFI committees.
2. **State AEFI Technical Collaborating Centres** – Each state must choose a medical college to function as state AEFI technical collaborating centre. The clinical specialists of the medical college (neurologists, cardiologists, respiratory medicine specialists in addition to paediatricians) and experts from the Department of Community Medicine will assist the state/state AEFI committee in conducting rapid causality assessments, case investigations in districts, laboratory tests in certain cases to find the cause of AEFIs, etc. These specialists (neurologists, cardiologists, respiratory medicine specialists, etc.) may be invited to attend AEFI committee meetings.
3. **Training of specialists of state AEFI committees and state AEFI technical collaborating centres for investigation and causality assessments** – The new committee members/ specialists should be oriented on the immunization programme, COVID19 vaccinations, AEFI surveillance and conduction of causality assessments for AEFI cases when they attend the AEFI committee meetings.
4. **More frequent meetings of state and district AEFI committees** – While state and district AEFI committees are required to meet once a quarter, in view of the need to clear the backlog of existing cases for investigations and causality assessments and to familiarise new members on AEFI surveillance processes and their roles and also to monitor the preparations for managing AEFI surveillance following COVID19 vaccinations, it is recommended that the AEFI committees meet at least once a month and share meeting minutes with the Immunization Division/AEFI Secretariat. The state AEFI committees should track whether district AEFI committee meetings are being held every quarter or more frequently, if required.
5. **Hiring of state AEFI consultants** – As COVID19 vaccinations are scaled up, there will be an increase in AEFI reporting due increased sensitization. All these cases need to be investigated, followed up for completion of documents

by the districts and causality assessed at the state level as soon as possible to elicit safety issues at the earliest for action. The following states were requested to ask for funds to hire state AEFI consultants in their PIP: Uttar Pradesh, Madhya Pradesh, Rajasthan, Bihar, Chhattisgarh, Jharkhand, Maharashtra, Gujarat, West Bengal, Andhra Pradesh, Telangana, Karnataka, Tamil Nadu and Odisha. While a few states have hired the consultant, others are requested to complete the process as soon as possible.

6. **Expanding reporting network of AEFI surveillance for adult vaccinations** – District Immunization Officers may be directed to
   a. Prepare a list of government and private hospitals and health care facilities, medical colleges, health care facilities of other ministries like railways, defense, ESIC, etc. in the districts and contact the head of the institutions to identify a Nodal Officer (AEFI reporting).
   b. Ensure that the Nodal Officer (AEFI reporting) conducts one-hour sensitization meetings with all doctors in the institutions to record vaccination history in OPDs, casualty/emergency consultations and in-patient admissions (focusing on medical, neurology, cardiology, respiratory medicine, obstetrics and gynaecology, in addition to paediatrics). Doctors should be able to report identified AEFIs immediately to the DIO and share clinical records of the case.
   c. Ensure that an AEFI register is available for medical officers to record minor, serious and severe AEFI details. The registers should be reviewed preferably daily by the Nodal Officer (AEFI reporting) or at least once a week. Any unreported serious/severe AEFIs should be reported to the DIO immediately. Each Nodal Officer (AEFI reporting) should have blank CRFs with them.
   d. Share the list of all such institutions with contact details of Nodal Officers (AEFI reporting) and dates of orientation of doctors to the state immunization officer for records.
7. **Operational PHC AEFI registers** – DIOs should ensure that AEFI registers are available at all planning units/cold chain points/ PHCs/CHCs/district hospitals and medical colleges and ANMs, medical officers and other staff are recording details of minor, serious and severe AEFIs in the register. These registers need to be reviewed weekly by the Nodal Officer (AEFI reporting) or medical officer in charge of the PHC/CHC. All forms and formats for reporting of AEFI cases are available at all health institutions.
8. **Adverse Drug Reaction Monitoring Centres (AMCs)** – Around 300 medical colleges and tertiary care hospitals across the country have Adverse Drug Reaction Monitoring Centres which report vaccine adverse events along with other adverse drug reactions. DIOs should contact such AMCs and request them to report serious and severe AEFIs directly. The current list of AMCs is available at https://ipc.gov.in/images/LIST_OF_311_AMC_UNDER_PvPI.pdf

9. **Ensure involvement of drug inspectors in investigations in the districts-** The drug inspector of the district should be a member of the district AEFI committee and may be involved in AEFI investigations, whenever required.
10. **Availability of injection adrenaline in Anaphylaxis and AEFI management kits and training of vaccinators on use of Anaphylaxis kits-** The districts should ensure that there is enough stock of injection Adrenaline for the coming months for use in Anaphylaxis kits and AEFI management kits. It is important to note that Adrenaline has short expiry date. It is also important that all vaccinators (including temporary hires for routine immunization and for COVID19 vaccinations) should be trained on use of the Anaphylaxis kits.
11. **AEFI trainings and sensitization meetings** – DIOs should initiate sensitization of medical officers and health workers in public and health facilities for immediate reporting of serious and severe AEFIs to the DIO and recording of minor, serious and severe AEFIs in AEFI registers. Monthly and weekly review meetings should be utilized for this purpose. The focus of sensitization should include AEFIs following adult vaccinations which will become important when COVID19 vaccinations are initiated. Data entry operators in the office of the DIO should be oriented on SAFEVAC, the online reporting software for AEFIs.
12. **Communication plans for vaccine safety** – Districts should prepare communication plans to manage rumours and myths regarding vaccine safety and crisis situations following serious AEFIs. Key messages for use in managing crisis situations and myths and rumours may be prepared in advance. Spokespersons may also be identified in advance and oriented on potential vaccine safety issues related to routine vaccines and potential COVID19 vaccines.

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डा. मनोहर अगनानी, भा.प्र.से.
अपर सचिव

DR. MANOHAR AGNANI , IAS
Additional Secretary

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

D.O. No. Z-16025/05/2012 lmm p/f
Dated the 22nd December 2020

This is in reference to the letter No. T-13020/08/2018-NIIM dated 18th November 2020 regarding initiatives to strengthen AEFI surveillance for COVID 19 vaccination. following action points has been recommended by National AEFI committee in a meeting held on 15th December 2020:

- **Inclusion of Obstetrics/Gynaecologist in the State/District AEFI committee.**
- **Contents of the AEFI Kit are revised**, which are annexed at Annexure I.
- **Training on use of Anaphylaxis kits for alternate vaccinators:** While it is expected that all vaccinators involved in UIP vaccinations are trained in use of Anaphylaxis kits, and therefore it is requested that all additional/alternate vaccinators including those from the private sector may be trained to identify suspected anaphylaxis and use contents of the Anaphylaxis kit.

For any additional information or support in implementing the above interventions you are kindly requested to contact Senior Zonal AEFI Consultant of your State/UT or local Surveillance Medical Officer (SMO) WHO-NPSP or the AEFI Secretariat.

Yours sincerely,

Encl: as above

(Dr. Manohar Agnani)

To,
Additional Chief Secretary/Secretary/Principal Secretary (Health) - All States/UTs

Room No. 145-A, Nirman Bhawan, New Delhi - 110011
Tel. : 011-23061723, E-mail : as-agnani@gov.in

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Copy to:

1. Mission Director (NHM) - All States/UTs
2. Chair, National AEFI Committee
3. Chairpersons of State AEFI Committees
4. Dr. Jai Prakash, Secretary-cum-Scientific Advisor (PC) - Indian Pharmacopoeia Commission, Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Govt. of India, Sector-23, Raj Nagar, Ghaziabad-201 002.
5. State Immunization Officer - All States/UTs
6. Dr Pankaj Bhatnagar, Acting Team Lead, WHO-NPSP
7. Dr Vineet Goyal, AEFI Focal Person, WHO-NPSP
8. Team Lead - AEFI, ITSU
9. Senior AEFI Zonal Consultants, MoH&FW, ITSU
10. PPS to AS&MD (NHM), MoH&FW
11. PPS to Joint Secretary (RCH), MoH&FW
12. PS to Adviser (RCH), MoH&FW
13. PS to Additional Commissioner (UIP), MoH&FW
14. PS to Joint Commissioner (Immunization), MoH&FW

(Dr. Manohar Agnani)

Annexure I

REVISED LIST OF CONTENTS OF AEFI MANAGEMENT KIT

The revised list of contents of the AEFI management kit for use at AEFI Management Centres is as follows:

1. Inj. Adrenaline (1:1000 dilution) - three ampoules
2. Tubercullin/insulin syringes - three
3. 24G/25G one inch needles - three
4. Cotton swab - three
5. Inj. Hydrocortisone – one
6. Ringer lactate/Normal saline – two units
7. 5% dextrose – two units
8. IV drip set – two units
9. Scalp vein sets or IV cannula – two
10. Disposable syringes – 5 ml with 24-25G 1M needles – three sets
11. Adhesive tape – one

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Dr. Mahesh Kumar Aggarwal
Additional Commissioner (UIP)
Tel.: 011-23062728, 23062125
E-mail : mk.aggarwal13@nic.in

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

D. O. No: Z.16025/02/2018-IMM
Dated: 05th January 2021

Dear Colleague

As part of the preparations for strengthening AEFI surveillance for introduction of COVID 19 vaccinations, an online training on investigation and causality assessment of Adverse Event Following Immunization of new members of national and state AEFI committee members is being held on 08 and 09 January 2021 from 2:00 pm to 5:30 pm.

You are requested to make it convenient to attend the training on both these days. The links, tentative agenda and other instructions for the training will be emailed directly to you. Please contact Dr Deepak Polpakara ([redacted], 9868878721) for clarifications.

Yours sincerely

05/01/21

(Dr M K Aggarwal)

To:

1. Dr. Sujata Mathews, Ram Manohar Lohia Hospital, New Delhi
2. Dr. Madhubala Negi, Ram Manohar Lohia Hospital, New Delhi
3. Dr. Alka Sharma, Ram Manohar Lohia Hospital, New Delhi
4. Dr Rupali Malik, Safdarjung Hospital, New Delhi
5. Dr Sameer Gulati, Safdarjung Hospital, New Delhi
6. Dr Aparna Agrawal, Lady Hardinge Medical College & Associated Hospitals, New Delhi
7. Dr Debashish Chaudhury, Lady Hardinge Medical College & Associated Hospitals, New Delhi
8. Dr Anupam Prakash Lady Hardinge Medical College & Associated Hospitals, New Delhi
9. Dr Ramesh Agrawal, Lady Hardinge Medical College & Associated Hospitals, N. Delhi
10. Dr Ritika Sud, Lady Hardinge Medical College & Associated Hospitals, New Delhi
11. Dr Vivek Suman, Lady Hardinge Medical College & Associated Hospitals, New Delhi
12. Dr Shubha Laxmi Margekar, Lady Hardinge Medical College & Associated Hospitals, New Delhi
13. Dr Priya Bansal, Lady Hardinge Medical College & Associated Hospitals, New Delhi
14. Dr Amit Kumar Sharma, Lady Hardinge Medical College & Associated Hospitals, New Delhi
15. Dr Sheikh Yasir Islam, Lady Hardinge Medical College & Associated Hospitals, New Delhi
16. Dr Shivraj Meena, Lady Hardinge Medical College & Associated Hospitals, New Delhi
17. Dr Manish Goyal, Lady Hardinge Medical College & Associated Hospitals, New Delhi

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Copy to:

1. Dr Anju Seth, Chair -Causality assessment sub-committee, National AEFI Committee
2. Dr S Aneja, Chair, National AEFI Committee
3. Dr Anil Gurtoo, Director-professor, Dept. of Medicine, LHMC
4. Dr Deepak Polpakara, Team Lead – AEFI, ITSU
5. All Senior Zonal AEFI Consultants, MOHFW

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डॉ. मनोहर अगनानी, भा.प्र.से.
अपर सचिव

DR. MANOHAR AGNANI , IAS
Additional Secretary

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011

GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

D.O. No. T.13020/05/2018-IMM
Dated the 9th February 2021

Dear All,

Since the initiation of the COVID 19 vaccination drive on 16th January 2021, some deaths following COVID 19 vaccination have been reported from districts. It is important that these reported deaths are investigated meticulously as per the National AEFI Guidelines. As you may be aware that Post Mortem procedure is a very important component of the investigation, therefore, kindly instruct the concerned officials to ensure that following guidelines are followed for conducting the Post-Mortem examinations: -

1. Post-Mortem should be conducted at the nearest Medical College Hospital or at the district level by a Forensic expert and Pathologist.
2. The process of post-mortem examination (external and internal) should be video-graphed.
3. The tissue samples (viscera) should be sent for histo-pathological examination in all cases and for toxicological analysis in specific cases to the designated medical college forensic science lab for analysis and followed up for early submission of reports

Properly conducted post-mortem reports with histo-pathological examination reports and toxicology analysis reports will help to conduct quality causality assessments of AEFI deaths. Therefore, these guidelines may kindly be conveyed to all the districts.

For any assistance or clarifications State/District Officials may contact the respective AEFI Zonal Senior Consultant or Dr Deepak Polpakara (deepak_polpakara@in.jsi.com).

With kind regards,

Yours sincerely,

09/02/2021

(Dr Manohar Agnani)

Additional Chief Secretary/Secretary/Principal Secretary (HFW), All States/UTs

Copy to:

1. Mission Director (NHM), all states/UTs.
2. SEPIO, all States/UTs
3. Chairperson, National AEFI Committee
4. Chairpersons of State AEFI Committees
5. Team Lead – AEFI, ITSU

Room No. 145-A, Nirman Bhawan, New Delhi - 110011
Tel. : 011-23061723, E-mail : as-agnani@gov.in

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राजेश भूषण, आईएएस
सचिव

RAJESH BHUSHAN, IAS
SECRETARY

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

D. O. No.2074697/2021/Immunization
12th February 2021

Dear Colleague,

The pan India rollout of Covid-19 vaccination has completed more than 3 weeks and covered approx. 7.5 million priority beneficiaries with first dose. In order to strengthen Adverse Effects Following Immunization (AEFI) surveillance following COVID-19 vaccination, it has already been communicated to States/UTs to ensure that State AEFI Committee meets at least once every fortnight to conduct the causality assessments and monitor the investigation reports of District AEFI Committees. District AEFI Committees are to meet more frequently, if required to undertake the investigation of AEFI cases post COVID-19 vaccination. It has, however, come to notice that in some States, State AEFI Committees are not meeting regularly.

It is, therefore, reiterated that State AEFI Committees should meet regularly to oversee the overall performance of AEFI Surveillance System so as to instil vaccine confidence in the community. Wherever, the State AEFI Committees feel the need to share feedback with National Level or require guidance from the MoHFW, Govt. of India, they may do so.

For any query, suggestion or support, States/UTs may contact the Senior Zonal AEFI Consultants of your State or AEFI Secretariat, MoHFW at aefiindia@gmail.com.

Warm Regards.

Yours sincerely,

(Rajesh Bhushan)

ACS(H)/Pr.Secy.(H)/Secy.(H) of all States/UTs

Room No. 156, A-Wing, Nirman Bhawan, New Delhi-110 011
Tele : (O) 011-23061863, 23063221, Fax : 011-23061252, E-mail : secyhfw@nic.in

(90)

T-13020/08/2016 - Imm
Ministry of Health and Family Welfare
Government of India
(Immunization Division)

Dated: 2 March 2021
Nirman Bhawan, New Delhi

To

Mission Director-NHM, all states and UTs

Subject: Conducting RTPCR tests in all death and hospitalized AEFI cases –reg.

Sir/Madam,

While conducting causality assessments of serious and severe AEFI cases following COVID 19 vaccinations at the national level, it has been noticed that the past history or current status of COVID 19 infection in reported AEFI cases (both hospitalizations and deaths) is not recorded in the Case Investigation Forms for AEFIs. As a result, it is not possible to conclusively rule out COVID 19 infection as a cause of illness post vaccination in hospitalized and death cases. There has also been a rise of COVID 19 infections in some states. Therefore, chances of COVID 19 cases reported as AEFIs post COVID 19 vaccination is possible.

The Special Group constituted to conduct expedited Causality Assessment of serious/severe AEFI cases reported following COVID 19 vaccinations has recommended that RTPCR tests are to be conducted in all hospitalized AEFI cases and also in death cases. RTPCR tests can be conducted using nasal swabs soon after death or during post mortem.

Therefore, it is requested that all health facilities in districts be instructed to ensure that RTPCR tests are conducted in all hospitalized and death cases of AEFIs and the results of the same be recorded in the Case Investigation Forms in Section B (past history) and Section C (test for COVID 19 infection after vaccination). A copy of the test reports (RTPCR) should also be shared with other records related to the case for causality assessment.

For any queries regarding this, you may contact the Senior AEFI Consultant of your state or Dr Deepak Polpakara (deepak_polpakara@in.jsi.com).

Yours faithfully,

(Dr. M K Aggarwal)

Copy to:

1. SEPIOs, all states and UTs
2. Chairpersons, State AEFI Committees, all states
3. Chairperson, National AEFI Committee
4. Chairperson, Special Group for COVID 19 Causality Assessment
5. Team Lead-AEFI, AEFI Secretariat, ITSU, New Delhi

(91)

T-13020/01/2013-CCV(Part1)
Ministry of Health and Family Welfare
Government of India
(Immunization Division)

Dated: 07th May, 2021
Nirman Bhawan, New Delhi

To

Mission Director (NHM),
All State's / UT's

Subject: Strengthening AEFI surveillance for COVID-19 vaccination –reg.

Madam/Sir,

You are aware that more than 16.49 crore COVID-19 vaccine doses have been administered till 06th May, 2021 as part of the measures to contain the COVID-19 pandemic. More than 24000 AEFI cases (95% of which are minor AEFIs) have been reported. Some of the recommendations of the National AEFI committee in its last meeting to strengthen reporting of AEFI cases following COVID-19 vaccines are as follows:

1. There is a gap in reporting of hospitalised AEFI cases, especially if the cases are treated in the private sector. The District Immunization Officer (DIO) should immediately report all AEFIs informed to them through any means (telephonic/email/letter/AEFI Case Reporting Forms, etc.) from hospitals in the public and private sector. The doctor or staff informing the AEFI may be provided blank CRFs for noting basic case details (**https://itsu.org.in/aefi/**). Also, all the AEFI case details should be entered in CoWIN-SAFEVAC as per the COVID-19 vaccination operational guidelines.
2. District Immunization Officer should ensure that her/his e mail details are available with all the prominent private healthcare facility for seamless reporting of serious/severe AEFI cases following COVID-19 vaccine. District Immunization Officer may also create a dedicated email for receiving reports of AEFI following COVID vaccination from Private and public health facilities.
3. Any case of hospitalization or death of a COVID positive (RT-PCR /CBNAAT/HRCT confirmed) case who has received at least one dose of vaccine before getting infected should be reported as a serious AEFI on Co-WIN.
4. Many AEFIs occurring beyond a week of vaccination are not being reported on Co-WIN-SAFEVAC. Reporting of any serious/severe adverse event occurring beyond one week of vaccination up to at least 28 days of COVID-19 vaccination should be encouraged
5. Regular State AEFI committee meetings are held and causality assessment of the reported serious/severe AEFI cases is completed as per the National COVID-19 guidelines.

For any further clarifications and guidance, please advise concerned State and District Officials to kindly contact the respective AEFI Zonal senior consultant or Dr Deepak Polpakara (deepak_polpakara@in.jsi.com).

Yours sincerely,

(Dr M K Aggarwal)
Additional Commissioner (UIP)

Copy to:

1. State Immunization Officers, All State's/UT's
2. Chair, National AEFI Committee
3. Chairpersons of State AEFI Committees
4. Team Lead – AEFI, ITSU
5. Senior AEFI Zonal Consultants, MoHFW
6. PS to JS (RCH)
7. PS to JC (Imm)

EXHIBIT "F" (92)

Gmail **Shubham Lunawat <shubhamlunawat98@gmail.com>**

Fwd: Regarding covid vaccine adverse reaction death to Dho Aurangabad

1 message

Shubham Lunawat <shubhamlunawat98@gmail.com> Thu, Apr 29, 2021 at 3:53 PM
To: dklunawat@rediffmail.com

---------- Forwarded message ---------
From: **Shubham Lunawat** <shubhamlunawat98@gmail.com>
Date: Sat 20 Mar, 2021, 1:13 AM
Subject: Regarding covid vaccine adverse reaction death
To: <dhoaurangabad@rediffmail.com>

Dear Sir ,
I am Shubham Lunawat brother of deseased Dr. Snehal Lunawat .Just to add the disclaimer before describing my case is she was healthier and fit with no significant medical history and medicines taken .

My sister took her first dose of Covishield on 28th January in Nasik. On 3rd of March she had a headache . She showed it to the doctors who diagnosed a mild Migrane of which she took medicines and felt fine. On 5th Feb she came to aurangabad to go to Delhi for attending a workshop in Gurgaon. She reached gurgaon on 6th afternoon and on the night of 7th Feb at 2am she had multiple episodes of vomitting till 8 am with fatigue. When she was rushed to hospital (Paras hospital, gurgaon) she was detected of bleeding in the brain.

She had bleeding, clot formation and low Platelets which are all signs of Covid virus or Covid vaccine . She was Covid negative after she was hospitalised. Doctors detected venous sinus thrombosis (Cloting) which was followed by intracranial bran hermmorage. They performed craniotomy and cloth removal surgery. She was on ventilator for 16 days in Gurgaon but her condition did not improve. Even doctors didn't know what is happening with her because it was a covid vaccine reaction and new to everyone. Even now many European nations have banned AstraZeneca's Covishield.

Then we brought her through ambulance to aurangabad , Ciigma hospital. She was on ventilator here for 8 days but condition didn't improve. She passed away on 1st March.

We want to report our case and want desired authorities to be responsible for it . We want to save future lives.

I'm attaching the case summary below of her

Awaiting your reply

New doc 22 Feb 2021 21.33-1.pdf
7618K

True Copy

Last Login Time : 2021-12-08 16:29:02 SL

Grievance Details

Grievance Number: 2627711

Grievance Reg Date: 2021-03-19 15:48:55

Complainant Name :	SAMRUDDHI LUNAWAT	**Complainant Contact No :**	9370556674
Mode :	By Web	**Complaint Type :**	Complaint
State :	MAHARASHTRA	**Purchase City :**	Nasik
Sector :	Health Services	**Category :**	Medical Negligence - Others
Grievance Company :		**Company Name :**	serum institute,pune
Govt Dept / Regulator :	Health & Family Welfare		
Company Details	serum institute,pune	**Pincode (Company):**	
Product Value(INR) :	NA	**Nature of Complaints :**	Death of Patient

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Last Login Time : 2021-12-08 16:29:02 SL

2021 in midnight she has a minor headache so on 5th Feb 2021 she approached the doctors available in the College itself for medication. Doctors told that there is a minor migraine and accordingly suggested the tablets to her. On 5th Feb 2021 she traveled to Aurangabad, Maharashtra and reached at 12 night being her home town. As she was to travel to Delhi for AIIMS workshop of 7 days she took a flight from Aurangabad to Delhi at reached Delhi at 3.30 PM on 6th Feb. At 2.00 AM on 6th Feb night she had headache and started to vomit and subsequently in morning she was admitted to Aryan Hospital whereby it was informed that there is a bleeding in the brain and so shifted to the Paras Hospital, Sector -43, Gurgaon. Neurosurgeons operated her for removable of skull and clot. For more details I am enclosing herewith the Case Summary of the Patient. When she was hospitalised We have written mailed to serum institute as well as to the Health Ministers for the Help but from serum no satisfactory report received and for other side no replies received. As the Patient was just aged 33 years and was having no medical history the only cause why this incidence happened was due to vaccination . Which resulted into death of the patient. Many such cases are reported in media as well but no cognizance for the same is taken. I am attaching herewith the Link of the cases happened and case summary of the patient for your reference. We request you to kindly provide us the financial assistance being family of the deceased as this is caused due to vaccination itself. I am not able to upload the case summary due to some technical errors on the portal.

Status : Disposed

Grievance Updated Details :	NCH out called the complainant on 20 Mar 2021 & 4:54 PM to discuss grievance details, as per the consumer her sister had taken vaccination of Covid 19, after that she faces headache issue & expired in the hospital because of vaccination. **Updation Date :**2021-03-20 17:02:16
NCH Agent Remark :	Advised her to raise greviance at the National Medical Commission. **Remark Date :**2021-03-20 17:02:16
Uploaded Files:	File1 | File2 | NA

Give your Feedback | Print

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Last Login Time : 2021-12-08 16:29:02 SL

(96)

No.Z.33014/28/2021-IMM
Government of India
Ministry of Health & Family Welfare
Immunization Section

साधारण डाक
BY ORDINARY POST

Nirman Bhawan, New Delhi
Dated the October, 2021

To

Shri Dilip Kisanlal Lunawat,
Tupadia Nagar, Durga Road,
Aurangabad, Ahmednagar,
Maharashtra.
(Email: dklunawat@rediffmail.com)

Subject: Online grievance Registration No. PMOPG/E/2021/0095402 dated 14.02.2021 - Reg.

Sir,

I am directed to refer to the above mentioned online grievance Registration No. PMOPG/E/2021/0095402 dated 14.02.2021 regarding Adverse Events Following Immunization (AEFI), under the AEFI surveillance system. Your concern was well noted.

2. It is submitted that the case records of all the reported serious and severe AEFI cases are examined, reviewed and causality assessment is done including the said case which may be seen at the following link:

https://main.mohfw.gov.in/Organisation/Departments-of-Health-and-Family-Welfare/Immunization/aefi-reports

Considering the importance of analyzing the AEFIs occurring due to COVID vaccination, a special group of experts has been constituted to rapidly review the AEFI cases for timely advice to States/UTs. A total of 498 cases were assessed by the group of trained medical experts and presented to NEGVAC (National Expert Group on Vaccine Administration for COVID-19). Based on this assessment an advisory was developed and shared by the members of the National AEFI Committee for dissemination among health care providers (for Diagnosing and treating Thrombosis and Thrombocytopenic Syndrome (TTS) occurring after administration of COVID-19 vaccine) and vaccinators (to encourage reporting of such events).

3. It is also pertinent to mention that guidance has been developed and advisories have already been issued to the States/UTs for timely diagnosis, management and reporting of AEFI cases occurring after administration of COVID-19 vaccine & for vaccine beneficiaries to encourage people to report such events to the health system, and seek medical help (copy enclosed). Details of the advisory in the Press Release are in the link below: https://www.pib.gov.in/PressReleseDetailm.aspx?PRID=1719293 –"Bleeding and clotting events following COVID vaccination miniscule in India - National AEFI (Adverse Event Following Immunization) Committee submits report to the Union Health Ministry" - Posted On: 17th May 2021 2:32 PM by PIB Delhi.

4. It is well known that there may be certain Adverse Events following Immunization, similar to side effects reported with other pharmaceutical products. However, the benefits of vaccinations far outweigh the risk of rare adverse events. The benefits of vaccination have been further exemplified during the current COVID-19 pandemic.

Yours faithfully,

(Thangkholun Haokip)
Under Secretary to the Govt. of India
Tel.:011-23063068

Enclosure: As above.

Copy to:

Section Officer (PG Cell), MoHFW, Nirman Bhawan with reference to Registration No. PMOPG/E/2021/0095402 dated 14.02.2021.

(97)

Advisory for vaccine beneficiaries

Thrombosis and Thrombocytopenia Syndrome (TTS) occurring after administration of COVISHIELD

Reports of rare cases of thrombosis (blood clotting) associated with thrombocytopenia (low platelet counts)—Thrombosis and Thrombocytopenia Syndrome (TTS) - have been reported globally following the use of some COVID 19 vaccinations particularly AstraZeneca vaccine (Covishield in India) and Johnson & Johnson's Janssen vaccine. The World Health Organization (WHO) and drug regulators of EU, UK and USA are investigating these reports (1, 2). A causal relationship between these rare events has not been established at this time though it is considered to be plausible by WHO (3).

A review of reported 498 serious and severe AEFI cases in India shows only a few cases clinically compatible with the diagnosis of TTS have been identified. Published literature shows that thromboembolic phenomenon is almost 70% less in South East Asian population compared to those of European descent (4, 5, 6).

Information for vaccine beneficiaries

A vaccine beneficiary vaccinated with any of the COVID-19 vaccines, particularly Covishield and having one or more of the symptoms mentioned below (see BOX) should be suspected to have Thrombosis and Thrombocytopenia Syndrome (TTS). (7)

Symptoms occurring within 20 days after receiving any COVID 19 vaccine
(Recipient should report to the health facility where vaccine was administered)

- Shortness of breath
- Chest Pain
- Pain in limbs / pain on pressing the limbs or swelling in the limbs (arm or calf)
- Multiple, pinhead size red spots or bruising of skin in an area beyond the injection site
- Persistent abdominal pain with or without vomiting
- Seizures in the absence of previous history of seizures with or without vomiting
- Severe and persistent headaches with or without vomiting (in the absence of previous history of migraine or chronic headache)
- Weakness/paralysis of limbs or any particular side or part of the body (includes cranial nerve involvements)
- Persistent vomiting without any obvious reason
- Blurred vision/ pain in eyes/Diplopia
- Mental status change / encephalopathy/ depressed level of consciousness
- Any other symptom or health condition which is of concern to the recipient or the family

Contraindications for the administration of COVISHIELD in the context of TTS:
Past history of major venous and arterial thrombosis occurring with thrombocytopenia.

The Ministry of Health and Family Welfare will continue to monitor the safety of all COVID-19 vaccines and promote reporting, investigation and monitoring of suspected adverse events. Covishield, the COVID-19 vaccine continues to have a positive benefit-risk profile, with tremendous potential to mitigate the severity of infections and reduce deaths due to COVID-19 across the world and in India. Over 15.3 crore doses of Covishield vaccine have been administered as of 08th May 2021 in India.

References:

1. EMA Statement: https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots
2. UK MHRA statement: https://www.gov.uk/government/news/mhra-regulator-confirms-that-people-should-continue-to-receive-the-covid-19-vaccine-astrazeneca
3. WHO-GACVS statement of 21 April: https://www.who.int/publications/m/item/who-2019-ncov-vaccines-SAGE_recommendation-AZD1222-2021.1
4. Lee LH, Gallus A, Jindal R, Wang C, Wu CC. Incidence of Venous Thromboembolism in Asian Populations: A Systematic Review. Thromb Haemost. 2017 Dec;117(12):2243-2260. doi: 10.1160/TH17-02-0134. Epub 2017 Dec 6. PMID: 29212112. https://pubmed.ncbi.nlm.nih.gov/29212112/
5. White RH, Keenan CR. Effects of race and ethnicity on the incidence of venous thromboembolism. Thromb Res. 2009;123 Suppl 4:S11-7. doi: 10.1016/S0049-3848(09)70136-7. PMID: 19303496. https://pubmed.ncbi.nlm.nih.gov/19303496/
6. ZAKAI, N.A. and McCLURE, L.A. (2011), Racial differences in venous thromboembolism. Journal of Thrombosis and Haemostasis, 9: 1877-1882. https://onlinelibrary.wiley.com/doi/full/10.1111/j.1538-7836.2011.04443.x
7. https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood

(99)

Advisory for healthcare service providers

Diagnosing and treating Thrombosis and Thrombocytopenic Syndrome (TTS) occurring after administration of COVISHIELD

Reports of rare cases of thrombosis associated with thrombocytopenia have been reported globally following the use of some COVID 19 vaccinations particularly AstraZeneca vaccine [Covishield in India] and Johnson & Johnson's Janssen vaccine. These cases have been reported to have occurred within two to three weeks of vaccination, mostly after the first dose; younger than 60 years and women were observed to have a higher risk of the problem. Drug regulators of EU, UK and USA are investigating these reports. A causal relationship between these rare events has not been established at this time[1]. WHO has stated[2] that a causal relationship between the ChAdOx-1S vaccine (AstraZeneca/Covishield) and Thrombosis with Thrombocytopenia Syndrome (TTS) (a very rare syndrome of blood clotting combined with low platelet count reported about 4 to 20 days following vaccination) is considered plausible although the biological mechanism for the syndrome is still being investigated.

India has reviewed 498 serious and severe adverse events following COVID-19 vaccinations to identify TTS - thromboembolic events (such as Cerebral Venous Sinus Thrombosis, Deep Vein Thrombosis and Pulmonary Embolism) in association with thrombocytopenia. Only a few cases clinically compatible with the diagnosis of TTS has been identified among these 498 cases that were reviewed. If these cases are considered as suspected TTS, the reporting rate of these events would be around 0.61/million doses, which is much lower than the 4 cases / million reported by UK's regulator (MHRA) or the 10 cases / million doses reported by Germany. Based on UK's reporting rate, there should have been 360 cases of TTS in India with 9 crore doses administered. Published literature shows that thromboembolic phenomenon is almost 70% less in South East Asian population compared to those of European descent[3,4,5].

Available AEFI data from India does not suggest any overall increase in clotting conditions such as deep venous thrombosis or pulmonary embolism following administration of COVID-19 vaccines. Reported rates of thromboembolic events after COVID-19 vaccines are in line with the expected number of

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[1] EMA Statement: https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-benefits-still-outweigh-risks-despite-possible-link-rare-blood-clots
UK MHRA statement: https://www.gov.uk/government/news/uk-regulator-confirms-that-people-should-continue-to-receive-the-covid-19-vaccine-astrazeneca

[2] WHO-GACVS statement of 21 April: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1

[3] Lee LH, Gallus A, Jindal R, Wang C, Wu CC. Incidence of Venous Thromboembolism in Asian Populations: A Systematic Review. Thromb Haemost. 2017 Dec;117(12):2243-2260. doi: 10.1160/TH17-02-0134. Epub 2017 Dec 6. PMID: 29212112. https://pubmed.ncbi.nlm.nih.gov/29212112/

[4] White RH, Keenan CR. Effects of race and ethnicity on the incidence of venous thromboembolism. Thromb Res. 2009;123 Suppl 4:S11-7. doi: 10.1016/S0049-3848(09)70136-7. PMID: 19303496. https://pubmed.ncbi.nlm.nih.gov/19303496/

[5] ZAKAI, N.A. and McCLURE, L.A. (2011), Racial differences in venous thromboembolism. Journal of Thrombosis and Haemostasis, 9: 1877-1882. https://onlinelibrary.wiley.com/doi/full/10.1111/j.1538-7836.2011.04443.x

diagnoses of these conditions. Both conditions occur naturally and are not uncommon. They also occur in patients with COVID-19 infection.

Information for healthcare professionals

Healthcare professionals should be alert to the signs and symptoms of TTS (thromboembolism and thrombocytopenia syndrome), so that they can promptly investigate and treat people affected in line with available guidelines.

Diagnosis and Management

Investigations for any suspected cases of thrombosis and thrombocytopenia:

- Blood
  - Platelet count <150x 10^3/L confirming *Thrombocytopenia*
  - Coagulation screen-raised D-Dimer values (>4000 mcg/L, suspect if the D-dimer level is 2000-4000 mcg/L)
  - Preserve serum sample for Antibodies to platelet factor 4 (PF4) which are detected using ELISA HIT assay.
- Radio-imaging studies
  - CT/MRI specifically for cerebro-vascular sinus thrombosis, haemorrhage, stroke
  - ECHO heart for pulmonary embolism
  - Radio-nucleotide studies and CT chest for pulmonary embolism
  - USG-doppler for thrombus in the portal, splenic, mesenteric veins
  - USG-doppler of the limbs for deep vein thrombosis (DVT)

Unlikely a case of TTS

- Thrombocytopenia without thrombosis with D-dimer normal or near normal and normal fibrinogen level
- Thrombosis with normal platelet count and D-dimer <2000 mcg/L and normal fibrinogen

Management of Thrombosis and Thrombocytopenic Syndrome (TTS) at a tertiary care hospital* such as District Hospital or Medical college, etc.

- Administer intravenous immunoglobulin (IV-Ig) urgently, 1 g/kg (divided into two days if needed) as this is the treatment most likely to influence the disease process.
- CORRECT fibrinogen levels if needed, to ensure level does not drop below 1.5 g/L, using fibrinogen concentrate or cryoprecipitate
- When fibrinogen is >1.5 g/L and platelets >30 x10^9/L consider starting anticoagulation. If anticoagulation is needed before then, critical illness dose Argatroban can be considered, initially without dose escalation and maintained at low dose.
- ANTICOAGULATE with non-heparin-based therapies such as DOACs (Direct-acting oral anti-coagulants), Argatroban, Fondaparinux or Danaparoid depending on the clinical picture. Bleeding and thrombotic risk needs to be carefully balanced and lower doses may be appropriate while platelet count is still low
- Steroids and plasma exchange should be considered and in particular if there is a delay in giving IV-Ig.
- If no overt thrombosis, but thrombocytopenia with raised D Dimer, thrombo-prophylaxis with non-heparin-based anticoagulants should be considered – balancing bleeding and thrombotic risk. DOAC, fondaparinux or danaparoid can be used.

***Ambulance services should be made available for transportation/referral of the patient to the tertiary care hospital.**

AVOID following interventions:

- Avoid platelet transfusions. Discuss any required interventions. If neurosurgery is required, this should not be delayed, and if the platelet count is <100 x10^9/L a platelet transfusion will be appropriate after, or with, IV-Ig.
- AVOID all forms of heparin including heparin-based flushes. (It is unknown whether heparin exacerbates the condition but until further data is clear, this is best avoided).
- Avoid thrombopoietin receptor agonists and Antiplatelet agents.

At discharge

- Continue anticoagulation for at least 3 months. If thrombosis was only arterial, once the D-dimer, platelets and fibrinogen have returned to normal, the patient can be switched to an antiplatelet agent and continued for three months.
- Monitor the platelet count periodically to observe for possible relapse.

Contraindications for the administration of COVISHIELD in the context of TTS:

Past history of major venous and arterial thrombosis occurring with thrombocytopenia.

Reporting of suspected TTS cases:

- Suspected cases of TTS occurring within 20 days of vaccination should be reported to the vaccinator or the District Immunization Officer (DIO) in the Case Reporting Format for further reporting on Co-WIN app.

Covishield, the COVID-19 vaccine continues to have a positive benefit-risk profile, with tremendous potential to mitigate the severity of infections and reduce deaths due to COVID-19 across the world and in India. Over 15.3 crore doses of Covishield vaccine have been administered as of 08th May 2021 in India. The Ministry of Health and Family Welfare will continue to monitor the safety of all COVID-19 vaccines and promote reporting of suspected adverse events.

References:

1. https://www.ema.europa.eu/en/news/astrazenecas-covid-19-vaccine-ema-finds-possible-link-very-rare-cases-unusual-blood-clots-low-blood
2. https://b-s-h.org.uk/media/19530/guidance-version-13-management-of-thrombosis-with-thrombocytopenia-occurring-after-c-19-vaccine-20210407.pdf
3. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca#pharmacodynamic-properties

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Details for registration number : PMOPG/E/2021/0095391

Name Of Complainant	Dr Snehal Dilip Lunawat
Date of Receipt	14/02/2021
Received By Ministry/Department	Prime Ministers Office

Grievance Description

Dear sir, my sister Dr Snehal Dilip Lunawat - have taken the vaccination on 28/01/2021 at SMBT College,Nasik and thereafter there was minor headache and fever on next day but on 4th of February she had again severe headache, vomitting hence after checking in SMBT college medical departments on 5th Feb, she has been given medicine of mild migraine. She came to Aurangabad on 5th night and further for her certificate conference she came to Delhi by flight reached @3.30 pm, on 6th Feb but on the same late night she had severe headache and unstoppable vomitting and due to weakness, she has to pickup by two/three people and send for hospitalisation in Gurgaon. I am enclosing the case summary in pdf for your research department.I would suggest that your research team should study the case and give fruitful outputs.There are very few cases which are actually reported in media with regards to the covishield vaccination. Similar cases has been observed in India too which is purely caused due to covishield vaccination. I request you to kindly provide us all type of support required. Below are the cases links around india, which are similar to our case.
https://www.cnbctv18.com/healthcare/16-deaths-reported-among-vaccine-recipients-govt-says-not-linked-to-vaccine-patient-groups-demand-more-data-8199491.htm

https://timesofindia.indiatimes.com/city/bengaluru/karnataka-asha-worker-dies-12-days-after-vaccination-in-belagavi/articleshow/80712499.cms

https://www.google.com/amp/s/www.thehindu.com/news/national/telangana/deaths-trigger-aefi-inquiry-job-land-promised-for-kin-of-ap-health-worker/article33649574.ece/amp/

I hope you will do
the needful for betterment of the society at large. If any further information required you can contact me.
we again request you to find out by your research team to stop further deaths due to vaccination. If you have any research done on thrombosis due to covishield please share with the doctors in paras Hospital, Sector 43, gurgaon where our patient is admitted and is in critical condition so that it might have the doctors to save her life.
We would suggest that serum institute research team should visit the hospital and do the need for betterment/improvement of our patient

Current Status	Case closed
Date of Action	09/06/2021

Remarks

As per the comments provided by the concerned department.

Officer Concerns To

Officer Name	Nilesh Falke ,UNDER SECRETARY
Organisation name	Prime Ministers Office
Contact Address	10 TH FLOOR G T HOSPITAL COMPOUND NEW MANTRALAYA MUMBAI
Email Address	nilesh.falke@nic.in
Contact Number	02222617510

Reminder(s) / Clarification(s)

Reminder Date	Remarks
10/03/2021	No reply received till date

Print Close

Gmail SAPNA LUNAWAT <sapnalunawat@gmail.com>

Request for sending AEFI Case Reporting Form and AEFI Case Investigation Form in case of Dr. Snehal Lunawat's case registered under AEFI

2 messages

SAPNA LUNAWAT <sapnalunawat@gmail.com> Tue, May 25, 2021 at 6:20 PM
To: dhonashik@gmail.com

Respected Sir,

I am Sapna Lunawat, sister of Dr. Snehal Lunawat whose case investigation under AEFI is under process. The AEFI registration number is INDMANA20214K7EA005WZ.

I request you to kindly share the copies of AEFI Case Investigation Form and AEFI Case Reporting Form of this case with me. Also, kindly update me the current status of the case.

I request you to keep updating me the status of this case stage by stage.

My contact number is 9325620758 or 9370556674 and mail id is sapnalunawat@gmail.com.

Thanks and Regards,

Sapna Dilip Lunawat.

SAPNA LUNAWAT <sapnalunawat@gmail.com> Thu, Jun 10, 2021 at 10:30 AM
To: dhonashik@gmail.com

As per the trailing mail, kindly send the AEFI Case Reporting Form and AEFI Case Investigation Form.

On Tue, 25 May 2021, 18:20 SAPNA LUNAWAT, <sapnalunawat@gmail.com> wrote:

> Respected Sir,
>
> I am Sapna Lunawat, sister of Dr. Snehal Lunawat whose case investigation under AEFI is under process. The AEFI registration number is INDMANA20214K7EA005WZ.
>
> I request you to kindly share the copies of AEFI Case Investigation Form and AEFI Case Reporting Form of this case with me. Also, kindly update me the current status of the case.
>
> I request you to keep updating me the status of this case stage by stage.
>
> My contact number is 9325620758 or 9370556674 and mail id is sapnalunawat@gmail.com.
>
> Thanks and Regards,
>
> Sapna Dilip Lunawat.

EXHIBIT" G " (109)

Source:mctlaw

$101 Million Award for Encephalopathy from MMR Vaccine

(July 17th, 2018. SARASOTA, FL) mctlaw attorneys negotiated a $101 million settlement for an infant who suffered a severe reaction to the MMR vaccine.

O.R.* was a one-year-old healthy baby girl who was already walking and climbing. On February 13, 2013, she received vaccinations for Measles Mumps Rubella (MMR), Hepatitis A, Haemophilus Influenzae type B (Hip), Prevnar (pneumonia), and Varicella (chickenpox).

That evening, the mother noticed baby O.R. was irritable and feverish. After a call to the pediatrician, the doctor advised Mom to give her Tylenol and Benadryl. The fever continued for several days and on the evening before her scheduled pediatrician visit, O.R. began having severe seizures.

She was rushed to the emergency room. Baby O.R. went into cardiac and respiratory arrest and doctors placed her on a ventilator.

The seizures and cardiac arrest left O.R. with a severe brain injury, encephalopathy, cortical vision impairment, truncal hypotonia (low muscle tone), and kidney failure.

After months of treatment at the hospital, baby O.R. finally went home, but her disabilities require specialized medical care and supervision around the clock for the rest of her life.

The $101 million-dollar settlement pays for the child's constant high-level medical care needed for the rest of her life. The family received a lump sum of $1 million dollars to cover the immediate costs of medical bills and expenses. The rest will be paid out through an annuity over the child's lifetime.

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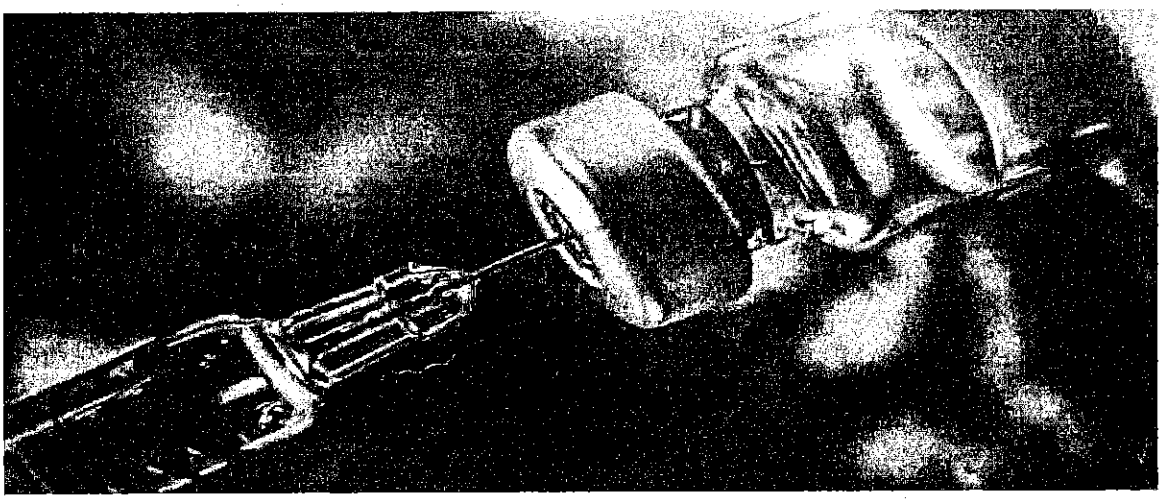

FILING THE VACCINE INJURY CLAIM IN FEDERAL COURT

Attorney Diana Stadelnikas represented the child and her parents in the National Vaccine Injury Compensation Program. Ms. Stadelnikas is an experienced Vaccine Injury Attorney and also a former Registered Nurse.

She filed a claim with the Vaccine Court on behalf of O.R. alleging the MMR immunization triggered the severe, but rare, reaction.

Stadelnikas filed the case in the U.S. Court of Claims against the Secretary of the Department of Health and Human Services (HHS). Upon reviewing the records and evidence, HHS conceded the case and agreed that O.R. was entitled to compensation for her vaccine-related injuries.

$101 MILLION VACCINE INJURY SETTLEMENT

The family received a lump sum of $1 million dollars to cover the immediate costs of medical bills and expenses from when the injury first happened.

The rest will be paid out through an annuity over the child's lifetime. Attorney's fees and costs are paid by the Vaccine Injury Compensation Program separately from the money awarded to the child.

You can read the actual decision on the Court of Federal Claims website: Case Number 16-119V: MMR Vaccine; Encephalopathy. Thankfully, this family reached out to our vaccine injury team and we were able to help them, says attorney Diana Stadelnikas. Vaccine injury cases are medically and legally complex; I cannot stress enough how important it is to work with an attorney who has experience representing injured families in the Vaccine Program to successfully navigate the complexities, urges Stadelnikas. The outcome here was a result of hard work, devotion, and the collaborative efforts of our experienced team.

OUR ATTORNEYS HAVE WON MILLIONS OF DOLLARS FOR OUR VACCINE INJURED CLIENTS.

Click to See More than 600 of Our Client Case Results

The attorneys at Maglio Christopher & Toale, P.A. have extensive experience representing people in the National Vaccine Injury Compensation Program (NVICP).

For almost 20 years the lawyers at our firm have helped people in all 50 states file vaccine injury claims. We have offices located in Washington, DC, Sarasota, FL and Seattle, WA. Our DC office is located two blocks from the Vaccine Court.

Vaccine injuries are not personal injury cases, they are a unique part of the Federal Court system. There are a small number of attorneys across the US who regularly practice in this court. MCT Law represents our clients in vaccine injury cases at no cost to them.

The NVICP pays attorney's fees separately from the victim's claim. This way, the victim keeps 100% of their award and never shares any part of it with their attorney. You can review a list of over 500 of our case results here:

https://www.mctlaw.com/vaccine-injury/cases/

In 1986 the federal government set up the National Vaccine Injury Compensation Program. This way, the government may compensate the small percentage of people who experience rare and severe vaccine reactions. As of June 2018, the program trust contains over $3.75 billion dollars to compensate patients who experience adverse vaccine reactions.

EXHIBIT "H" (108)

Z-16025/05/2012 Imm p/f
Government of India
Ministry of Health & Family Welfare
Immunization Division

Nirman Bhawan, New Delhi
Date: 07th December 2021

Causality assessment results of 178 reported Serious Adverse Events Following Immunization (AEFI) cases following COVID-19 vaccination approved by National AEFI Committee on 22nd November 2021.

The Immunization Division, MoHFW has taken several steps to strengthen the national AEFI surveillance system for COVID-19 vaccinations. Considering the importance and critical nature of the task, steps were taken to include medical specialists, cardiologists, neurologists, pulmonary medicine specialists, obstetrician-gynecologist as members of the causality assessment sub-committee at the national level. A Special Group has been framed to conduct causality assessment of AEFIs following COVID-19 vaccination. The results of causality assessment done by this Special Group is discussed in the national AEFI committee meeting for final approval.

The results of the causality assessment for 178 cases completed on 22nd November 2021 after thorough review, deliberation and approval by the National AEFI Committee is given in the annexure (anonymized line list of the causality assessment done by the National AEFI Committee).

67 out of 178 cases for which Causality assessment has been done were found to have **consistent causal association to vaccination.** Of these 67 cases, 52 cases were vaccine product related reaction including 04 deaths and 15 cases were immunization anxiety related reaction. 77 cases have inconsistent causal association to vaccination (**coincidental - not linked to vaccination**), including 33 death cases. 30 cases were in indeterminate category including 03 death cases. There were 04 cases in unclassifiable category, including 03 death cases.

Vaccine product related reactions are expected reactions that can be attributed to vaccination based on current scientific evidence. Examples of such reactions are allergic reactions and anaphylaxis, etc.

Indeterminate reactions are reactions which have occurred soon after vaccination but there is no definitive evidence in current literature or clinical trial data that this event could have been caused due to the vaccine. Further observations, analysis and studies are required.

Unclassifiable events are events which have been investigated but there is not enough evidence for assigning a diagnosis due to missing crucial information. When this relevant information becomes available, the case may be reconsidered for causality assessment.

Coincidental events are events that are reported following immunization but for which a clear cause other than vaccination is found on investigation.

Overall, the benefits of vaccination are overwhelmingly greater than the small risk of harm. However, as a measure of utmost precaution, all emerging signals of harm are being constantly tracked and reviewed periodically.

True Copy

CAUSALITY CLASSIFICATION OF 178 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 22 NOV 2021- (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION

C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(s), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE

D - UNCLASSIFIABLE

SR. NO.	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION BY THE NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
1	IND(CO-AEFI)CGMMD21002	2021	44	FEMALE	HOSPITALIZED & RECOVERED	30-01-2021	COVISHIELD	ACUTE TRANSVERSE MYELITIS	B1	22-Nov-21
2	IND(CO-AEFI)HAJND21001	2021	35	FEMALE	SEVERE & RECOVERED	23-01-2021	COVISHIELD	FACIAL PALSY	B1	22-Nov-21
3	IND(CO-AEFI)KASHI21002	2021	35	FEMALE	HOSPITALIZED & RECOVERED	25-01-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
4	IND(CO-AEFI)KAGBG21001	2021	23	FEMALE	HOSPITALIZED & RECOVERED	05-02-2021	COVISHIELD	SEIZURE (KNOWN PATIENT OF SEIZURES AND WAS ON TAPERING DOSE OF PHENYTOIN)	C	22-Nov-21
5	IND(CO-AEFI)MPSVP21001	2021	23	FEMALE	HOSPITALIZED & RECOVERED	27-01-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
6	IND(CO-AEFI)MHBMC21009	2021	42	FEMALE	HOSPITALIZED & RECOVERED	25-01-2021	COVISHIELD	COVID INFECTION	C	22-Nov-21
7	IND(CO-AEFI)PDPNY21001	2021	47	FEMALE	HOSPITALIZED & RECOVERED	09-02-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
8	IND(CO-AEFI)PBSAN21007	2021	33	MALE	HOSPITALIZED & RECOVERED	16-01-2021	COVISHIELD	FEVER	A1	22-Nov-21
9	IND(CO-AEFI)SIEST21003	2021	29	FEMALE	HOSPITALIZED & RECOVERED	19-01-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
10	IND(CO-AEFI)UAHRD21001	2021	32	FEMALE	HOSPITALIZED & RECOVERED	16-01-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
11	IND(CO-AEFI)WBRMH21002	2021	37	MALE	SEVERE & RECOVERED	22-01-2021	COVISHIELD	FEVER	A1	22-Nov-21
12	IND(CO-AEFI)WBHGL21001	2021	48	FEMALE	HOSPITALIZED & RECOVERED	17-02-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
13	IND(CO-AEFI)TSMBR21001	2021	36	FEMALE	HOSPITALIZED & RECOVERED	16-02-2021	COVISHIELD	ACUTE ISCHAEMIC THROMBOEMBOLIC INFARCT IN A KNOWN CASE OF DIABETES MELLITUS AND RHEUMATIC HEART DISEASE	C	22-Nov-21
14	IND(CO-AEFI)KEKNU21001	2021	24	FEMALE	DEATH	03-02-2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME LIKE ILLNESS WITH COVID 19 INFECTION	B2	22-Nov-21
15	IND(CO-AEFI)WBCAL21017	2021	43	MALE	HOSPITALIZED & RECOVERED	13-02-2021	COVISHIELD	VASOVAGAL SYNCOPE	A4	22-Nov-21
16	IND(CO-AEFI)MHBMC21016	2021	55	MALE	HOSPITALIZED & RECOVERED	19-02-2021	COVISHIELD	ISCHAEMIC HEART DISEASE WITH PREVIOUS HISTORY OF SIMILAR EPISODE	C	22-Nov-21
17	IND(CO-AEFI)MHBMC21018	2021	58	MALE	HOSPITALIZED & RECOVERED	28-01-2021	COVISHIELD	FACIAL PALSY	B1	22-Nov-21
18	IND(CO-AEFI)MHBMC21019	2021	27	FEMALE	HOSPITALIZED & RECOVERED	20-02-2021	COVISHIELD	ALLERGIC RASH WITH FEVER	A1	22-Nov-21
19	IND(CO-AEFI)ORGJM21002	2021	56	FEMALE	HOSPITALIZED & RECOVERED	25-02-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
20	IND(CO-AEFI)KEWYD21002	2021	39	FEMALE	SEVERE & RECOVERED	29-01-2021	COVISHIELD	FACIAL PALSY	B1	22-Nov-21
21	IND(CO-AEFI)ORSUN21003	2021	24	FEMALE	HOSPITALIZED & RECOVERED	18-01-2021	COVISHIELD	FEVER, BODYACHE, VOMITTING, FATIGUE AND VERTIGO	A1	22-Nov-21
22	IND(CO-AEFI)UPBRP21001	2021	71	MALE	HOSPITALIZED & RECOVERED	04-03-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
23	IND(CO-AEFI)MHBMC21022	2021	51	MALE	SEVERE & RECOVERED	22-02-2021	COVISHIELD	LEFT 3RD NERVE PALSY (PUPIL SPARING) INCOMPLETE	C	22-Nov-21
24	IND(CO-AEFI)MHBMC21001	2021	39	FEMALE	HOSPITALIZED & RECOVERED	22-01-2021	COVISHIELD	FEVER WITH GENERALISED WEAKNESS	A1	22-Nov-21
25	IND(CO-AEFI)ORNUP21002	2021	26	FEMALE	HOSPITALIZED & RECOVERED	23-01-2021	COVISHIELD	FEVER WITH HEADACHE	A1	22-Nov-21
26	IND(CO-AEFI)ORKRD21002	2021	52	FEMALE	HOSPITALIZED & RECOVERED	21-01-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
27	IND(CO-AEFI)GURJT21003	2021	25	FEMALE	HOSPITALIZED & RECOVERED	28-01-2021	COVISHIELD	SEIZURE	D	22-Nov-21
28	IND(CO-AEFI)TRTRW21005	2021	46	FEMALE	HOSPITALIZED & RECOVERED	04-02-2021	COVISHIELD	FEVER	A1	22-Nov-21
29	IND(CO-AEFI)MHBMC21002	2021	47	FEMALE	HOSPITALIZED & RECOVERED	25-01-2021	COVISHIELD	FEVER, MALAISE & VOMITTING	A1	22-Nov-21
30	IND(CO-AEFI)GUBVN21001	2021	35	FEMALE	SEVERE & RECOVERED	19-01-2021	COVISHIELD	FEVER	A1	22-Nov-21
31	IND(CO-AEFI)HPHMR21001	2021	56	FEMALE	DEATH	29-01-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B2	22-Nov-21
32	IND(CO-AEFI)UPSHP21001	2021	28	MALE	HOSPITALIZED & RECOVERED	04-02-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
33	IND(CO-AEFI)APPKM21001	2021	24	FEMALE	HOSPITALIZED & RECOVERED	23-01-2021	COVISHIELD	SEPSIS WITH PYELONEPHRITIS WITH ACUTE KIDNEY INJURY	C	22-Nov-21
34	IND(CO-AEFI)TRTRW21006	2021	25	MALE	HOSPITALIZED & RECOVERED	11-02-2021	COVISHIELD	ENCEPHALOMALACIA WITH GLIOSIS	C	22-Nov-21
35	IND(CO-AEFI)TSMDK21001	2021	42	FEMALE	HOSPITALIZED & RECOVERED	19-01-2021	COVISHIELD	SEIZURE DISORDER	C	22-Nov-21
36	IND(CO-AEFI)WBCAL21007	2021	51	FEMALE	HOSPITALIZED & RECOVERED	16-01-2021	COVISHIELD	ACUTE FEBRILE ILLNESS	A1	22-Nov-21
37	IND(CO-AEFI)WBCAL21010	2021	40	MALE	SEVERE & RECOVERED	19-01-2021	COVISHIELD	FEVER WITH ARTHRALGIA	A1	22-Nov-21
38	IND(CO-AEFI)KAUDU21002	2021	52	MALE	HOSPITALIZED & RECOVERED	09-02-2021	COVISHIELD	VIRAL PNEUMONIA	C	22-Nov-21
39	IND(CO-AEFI)WBCAL21011	2021	49	MALE	SEVERE & RECOVERED	29-01-2021	COVISHIELD	FACIAL PALSY	B1	22-Nov-21

CAUSALITY CLASSIFICATION OF 178 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 22 NOV 2021- (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION

C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(s), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE

D - UNCLASSIFIABLE

S NO	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/ OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
40	IND(CO-AEFI)HAPKL21001	2021	46	FEMALE	SEVERE & RECOVERED	25-01-2021	COVISHIELD	BILATERAL CENTRAL RETINAL VEIN OCCLUSION	B1	22-Nov-21
41	IND(CO-AEFI)HAPKL21002	2021	37	MALE	SEVERE & RECOVERED	05-02-2021	COVISHIELD	UNCONTROLLED DIABETES WITH ANTERIOR UVEITIS AND RETINOPATHY	C	22-Nov-21
42	IND(CO-AEFI)KADHA21002	2021	40	FEMALE	HOSPITALIZED & RECOVERED	10-02-2021	COVISHIELD	BILATERAL PNEUMONIA WITH DIABETES MELLITUS	C	22-Nov-21
43	IND(CO-AEFI)KAMYS21003	2021	41	MALE	HOSPITALIZED & RECOVERED	12-02-2021	COVISHIELD	DIABETIC KETOACIDOSIS WITH HYPOTHYROIDISM WITH FOCAL SEIZURE	C	22-Nov-21
44	IND(CO-AEFI)WBMBD21003	2021	40	FEMALE	SEVERE & RECOVERED	25-01-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
45	IND(CO-AEFI)DLWES21007	2021	27	MALE	HOSPITALIZED & RECOVERED	23-02-2021	COVISHIELD	BRONCHIAL ASTHMA WITH ACUTE EXACERBATION	C	22-Nov-21
46	IND(CO-AEFI)UPBRL21004	2021	31	FEMALE	SEVERE & RECOVERED	29-01-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
47	IND(CO-AEFI)CGBTR21001	2021	23	FEMALE	HOSPITALIZED & RECOVERED	04-02-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
48	IND(CO-AEFI)KEKZK21003	2021	62	FEMALE	HOSPITALIZED & RECOVERED	02-02-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
49	IND(CO-AEFI)HAFBD21001	2021	77	FEMALE	DEATH	06-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME IN A KNOWN CASE OF DIABETES MELLITUS	C	22-Nov-21
50	IND(CO-AEFI)MHBMC21027	2021	87	MALE	HOSPITALIZED & RECOVERED	11-02-2021	COVISHIELD	COVID-19 DISEASE	C	22-Nov-21
51	IND(CO-AEFI)MHBMC21026	2021	77	MALE	HOSPITALIZED & RECOVERED	04-03-2021	COVISHIELD	CEREBROVASCULAR ACCIDENT WITH DIABETES MELLITUS	C	22-Nov-21
52	IND(CO-AEFI)TNVPM21001	2021	76	FEMALE	DEATH	06-03-2021	COVISHIELD	ACUTE GASTROENTERITIS WITH HYPOGLYCAEMIA, WITH DYSELECTROLAEMIA, WITH METABOLIC ENCEPHALOPATHY WITH ATRIAL FIBRILATION	C	22-Nov-21
53	IND(CO-AEFI)BICPW21003	2021	74	FEMALE	DEATH	08-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME WITH DIABETES MELLITUS, HYPERTENSION AND ASTHMA	C	22-Nov-21
54	IND(CO-AEFI)WBMBD21008	2021	63	MALE	HOSPITALIZED & RECOVERED	10-03-2021	COVISHIELD	HEMOPTYSIS	C	22-Nov-21
55	IND(CO-AEFI)BIAGB21001	2021	45	FEMALE	DEATH	08-03-2021	COVISHIELD	SUDDEN UNEXPLAINED DEATH	D	22-Nov-21
56	IND(CO-AEFI)SIEST21001	2021	36	FEMALE	HOSPITALIZED & RECOVERED	20-01-2021	COVISHIELD	ACUTE FEBRILE ILLNESS WITH HEADACHE AND MYALGIA	A1	22-Nov-21
57	IND(CO-AEFI)WBDJL21007	2021	22	MALE	SEVERE & RECOVERED	29-01-2021	COVISHIELD	CHILLS WITH NAUSEA	A1	22-Nov-21
58	IND(CO-AEFI)APPKM21003	2021	39	FEMALE	DEATH	21-01-2021	COVISHIELD	MULTIPLE MYELOMA, SEPSIS, ACUTE ON CHRONIC KIDNEY DISEASE	C	22-Nov-21
59	IND(CO-AEFI)WBSPG21010	2021	77	MALE	DEATH	09-03-2021	COVISHIELD	UNEXPLAINED DEATH	D	22-Nov-21
60	IND(CO-AEFI)APEGV21002	2021	87	MALE	DEATH	15-03-2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH DIABETES MELLITUS	C	22-Nov-21
61	IND(CO-AEFI)GUGIR21001	2021	40	FEMALE	HOSPITALIZED & RECOVERED	25-02-2021	COVISHIELD	SEIZURE DISORDER	C	22-Nov-21
62	IND(CO-AEFI)HPMND21002	2021	69	MALE	HOSPITALIZED & RECOVERED	09-03-2021	COVISHIELD	MODERATE COVID 19 DISEASE	C	22-Nov-21
63	IND(CO-AEFI)JHRNC21005	2021	35	MALE	HOSPITALIZED & RECOVERED	10-03-2021	COVISHIELD	ACUTE INFERO POSTERIOR WALL MYOCARDIAL INFARCTION	B1	22-Nov-21
64	IND(CO-AEFI)SISTH21001	2021	64	FEMALE	DEATH	03-03-2021	COVISHIELD	HYPERTENSION WITH COPD WITH ACUTE EXACERBATION WITH LOWER RESPIRATORY TRACT INFECTION WITH RESPIRATORY FAILURE	C	22-Nov-21
65	IND(CO-AEFI)GOGOS21002	2021	39	FEMALE	SEVERE & RECOVERED	02-02-2021	COVISHIELD	FEVER WITH LOCAL SITE PAIN	A1	22-Nov-21
66	IND(CO-AEFI)APPKM21004	2021	78	MALE	DEATH	08-03-2021	COVISHIELD	CORONARY ARTERY DISEASE WITH ANTERIOR WALL MYOCARDIAL INFARCTION WITH TYPE 2 DIABETES MILLETUS WITH HYPERTENSION WITH CARDIOGENIC SHOCK	C	22-Nov-21
67	IND(CO-AEFI)APVSM21001	2021	39	FEMALE	DEATH	05-03-2021	COVISHIELD	GULLIAN BARRE SYNDROME WITH PNEUMONIA	B1	22-Nov-21
68	IND(CO-AEFI)KEPLK21003	2021	40	FEMALE	HOSPITALIZED & RECOVERED	04-03-2021	COVISHIELD	ACUTE DISSEMINATED ENCEPHALOMYELITIS	B1	22-Nov-21
69	IND(CO-AEFI)CGMGL21001	2021	51	FEMALE	HOSPITALIZED & RECOVERED	08-03-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
70	IND(CO-AEFI)WBNDG21001	2021	71	FEMALE	DEATH	19-03-2021	COVISHIELD	ACUTE ANTERIOR WALL MYOCARDIAL INFARCTION WITH TYPE II DIABETES MELLITUS	C	22-Nov-21
71	IND(CO-AEFI)GOGON21003	2021	35	MALE	HOSPITALIZED & RECOVERED	15-02-2021	COVISHIELD	MILD COVID DISEASE	C	22-Nov-21

CAUSALITY CLASSIFICATION OF 178 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 22 NOV 2021- (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

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S. NO.	CASE ID (NATIONAL ID)	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
72	IND(CO-AEFI)KEPTM21003	2021	81	FEMALE	HOSPITALIZED & RECOVERED	20-03-2021	COVISHIELD	ACUTE INFERIOR WALL MYOCARDIAL INFARCTION WITH UNDERLYING DIABETES, HYPERTENSION & DYSLIPIDEMIA.	C	22-Nov-21
73	IND(CO-AEFI)HAHSR21004	2021	68	FEMALE	DEATH	22-03-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
74	IND(CO-AEFI)HAKTL21001	2021	61	FEMALE	HOSPITALIZED & RECOVERED	18-03-2021	COVISHIELD	ACCELERATED HYPERTENSION	C	22-Nov-21
75	IND(CO-AEFI)WBSPG21002	2021	66	MALE	DEATH	19-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME WITH UNDRLYING DIABETES, HYPERTENSION AND CHRONIC SMOKING	C	22-Nov-21
76	IND(CO-AEFI)UPBDH21001	2021	73	MALE	DEATH	17-03-2021	COVISHIELD	COVID 19 DISEASE WITH ACUTE RESPIRATORY DISTRESS SYNDROME WITH UNDERLYING DIABETES MELLITUS AND HYPERTENSION	C	22-Nov-21
77	IND(CO-AEFI)UPBBK21001	2021	55	MALE	HOSPITALIZED & RECOVERED	17-03-2021	COVISHIELD	FEVER AND BODY ACHE	A1	22-Nov-21
78	IND(CO-AEFI)MPBPL21001	2021	35	FEMALE	SEVERE & RECOVERED	16-01-2021	COVISHIELD	ACUTE FEBRILE ILLNESS	A1	22-Nov-21
79	IND(CO-AEFI)MPBTL21001	2021	32	MALE	HOSPITALIZED & RECOVERED	11-02-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
80	IND(CO-AEFI)KABEL21008	2021	76	MALE	DEATH	26-03-2021	COVISHIELD	ACUTE MYOCARDIAL INFARCTION IN A KNOWN CASE OF DIABETES MELLITUS AND HYPERTENSION.	C	22-Nov-21
81	IND(CO-AEFI)DLNDL21004	2021	61	MALE	DEATH	25-03-2021	COVISHIELD	ACUTE CORONARY SYNDROME LEADING TO MYOCARDIAL INFARCTION AND PULMONARY EDEMA	C	22-Nov-21
82	IND(CO-AEFI)GOGOS21005	2021	63	MALE	HOSPITALIZED & RECOVERED	24-03-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
83	IND(CO-AEFI)GOGOS21006	2021	62	MALE	HOSPITALIZED & RECOVERED	09-03-2021	COVISHIELD	COVID 19 DISEASE	C	22-Nov-21
84	IND(CO-AEFI)KEAPZ21017	2021	63	MALE	HOSPITALIZED & RECOVERED	27-03-2021	COVISHIELD	CORONARY ARTERY DISEASE WITH ACUTE CORONARY SYNDROME (NSTEMI)	C	22-Nov-21
85	IND(CO-AEFI)RJSKR21001	2021	66	MALE	DEATH	26-03-2021	COVISHIELD	ACUTE MYOCARDIAL INFARCTION with underlying COPD and chronic smoking	C	22-Nov-21
86	IND(CO-AEFI)MPBRW21003	2021	59	FEMALE	DEATH	03-02-2021	COVISHIELD	SEVERE COVID 19 DISEASE	C	22-Nov-21
87	IND(CO-AEFI)UPHTR21001	2021	50	FEMALE	HOSPITALIZED & RECOVERED	28-01-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
88	IND(CO-AEFI)WBCAL21026	2021	74	MALE	HOSPITALIZED & RECOVERED	30-03-2021	COVISHIELD	FEVER, JOINT PAIN, VOMITTING AND SYNCOPE.	A1	22-Nov-21
89	IND(CO-AEFI)WBMBD21012	2021	63	MALE	DEATH	31-03-2021	COVISHIELD	ACUTE MYOCARDIAL INFARCTION WITH PREVIOUS HISTORY OF CORONARY ARTERY DISEASE AND CHRONIC SMOKER	C	22-Nov-21
90	IND(CO-AEFI)KEAPZ21007	2021	68	MALE	DEATH	12-03-2021	COVISHIELD	SEVERE COVID 19 PNEUMONIA WITH RESPIRATORY FAILURE WITH UNDERLYING DIABETES, HYPERTENSION AND CORONARY ARTERY DISEASE WITH RENAL FAILURE	C	22-Nov-21
91	IND(CO-AEFI)MPBRW21004	2021	67	MALE	DEATH	01-04-2021	COVISHIELD	SEVERE COVID DISEASE	C	22-Nov-21
92	IND(CO-AEFI)ORNRP21002	2021	66	MALE	DEATH	01-04-2021	COVISHIELD	SUDDEN CARDIAC DEATH WITH POST MORTEM CONFIRMED ATHEROVASCULAR DISEASE	C	22-Nov-21
93	IND(CO-AEFI)KEAPZ21008	2021	56	MALE	DEATH	06-03-2021	COVISHIELD	ACUTE MYOCARDIAL INFARCTION with underlying Diabetes	C	22-Nov-21
94	IND(CO-AEFI)TNCNI21006	2021	33	MALE	HOSPITALIZED & RECOVERED	03-03-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
95	IND(CO-AEFI)KABMP21017	2021	66	MALE	HOSPITALIZED & RECOVERED	06-03-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
96	IND(CO-AEFI)WBMBD21015	2021	45	FEMALE	HOSPITALIZED & RECOVERED	23-03-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
97	IND(CO-AEFI)MPMDL21003	2021	73	FEMALE	HOSPITALIZED & RECOVERED	22-03-2021	COVISHIELD	COVID 19 DISEASE WITH UNDERLYING HYPERTENSION	C	22-Nov-21
98	IND(CO-AEFI)MHBMC21041	2021	68	FEMALE	SEVERE & RECOVERED	26-03-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
99	IND(CO-AEFI)WBDMD21008	2021	34	MALE	SEVERE & RECOVERED	05-03-2021	COVISHIELD	MILD COVID 19 INFECTION	C	22-Nov-21
100	IND(CO-AEFI)CGRGH21002	2021	65	FEMALE	HOSPITALIZED & RECOVERED	17-03-2021	COVISHIELD	HYPERTENSION	C	22-Nov-21
101	IND(CO-AEFI)TNCNI21009	2021	59	FEMALE	HOSPITALIZED & RECOVERED	19-01-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21

CAUSALITY CLASSIFICATION OF 178 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 22 NOV 2021- (NEW DELHI)

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S. NO.	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/ OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
102	IND(CO-AEFI)WBBDNZ1011	2021	58	FEMALE	HOSPITALIZED & RECOVERED	03-04-2021	COVISHIELD	FEVER, NAUSEA, VOMITING	A1	22-Nov-21
103	IND(CO-AEFI)GOGONZ1008	2021	56	MALE	HOSPITALIZED & RECOVERED	24-03-2021	COVISHIELD	COVID 19 PNEUMONIA WITH HYPERTENSION AND TYPE 2 DIABETES MELLITUS	C	22-Nov-21
104	IND(CO-AEFI)RJUDPZ1003	2021	61	MALE	HOSPITALIZED & RECOVERED	03-04-2021	COVISHIELD	NSTEMI WITH BILATERAL ATYPICAL PNEUMONITIS WITH HYPERTENSION, DIABETES MELLITUS AND LEFT VENTRICULAR HYPERTROPHY	C	22-Nov-21
105	IND(CO-AEFI)UPMRDZ1006	2021	49	MALE	HOSPITALIZED & RECOVERED	05-04-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
106	IND(CO-AEFI)GOGOSZ1008	2021	87	FEMALE	HOSPITALIZED & RECOVERED	04-03-2021	COVISHIELD	TYPE 2 DIABETES MELLITUS WITH ALZHEIMER WITH HYPERTENSIVE EMERGENCY WITH LEFT VENTRICULAR FAILURE	C	22-Nov-21
107	IND(CO-AEFI)UPBJNZ1004	2021	67	MALE	DEATH	01-04-2021	COVAXIN	UNEXPLAINED DEATH	D	22-Nov-21
108	IND(CO-AEFI)KEKNUZ1007	2021	24	FEMALE	HOSPITALIZED & RECOVERED	25-02-2021	COVISHIELD	MILD COVID 19 DISEASE	C	22-Nov-21
109	IND(CO-AEFI)GOGONZ1009	2021	55	MALE	HOSPITALIZED & RECOVERED	18-03-2021	COVISHIELD	MODERATE COVID 19 DISEASE WITH HYPERTENSION	C	22-Nov-21
110	IND(CO-AEFI)GOGONZ1010	2021	46	MALE	HOSPITALIZED & RECOVERED	20-03-2021	COVISHIELD	MILD COVID 19 DISEASE IN A KNOWN CASE OF DIABETES MELLITUS	C	22-Nov-21
111	IND(CO-AEFI)KAMYSZ1007	2021	51	MALE	HOSPITALIZED & RECOVERED	26-03-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
112	IND(CO-AEFI)WBUDJZ1006	2021	55	MALE	DEATH	06-03-2021	COVISHIELD	COVID 19 DISEASE, PNEUMONIA AND ARDS	C	22-Nov-21
113	IND(CO-AEFI)HPMNDZ1005	2021	61	MALE	DEATH	12-04-2021	COVISHIELD	ACUTE MYOCARDIAL INFARCTION WITH POST MORTEM CONFIRMED ATHEROVASCULAR DISEASE	C	22-Nov-21
114	IND(CO-AEFI)WBBDNZ1013	2021	60	FEMALE	DEATH	26-03-2021	COVISHIELD	COVID 19 DISEASE WITH HYPERTENSION AND HYPOTHYROIDISM	C	22-Nov-21
115	IND(CO-AEFI)WBBDNZ1012	2021	50	FEMALE	HOSPITALIZED & RECOVERED	03-04-2021	COVISHIELD	FEVER AND GASTRITIS	A1	22-Nov-21
116	IND(CO-AEFI)UPMAIZ1001	2021	37	FEMALE	SEVERE & RECOVERED	05-02-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
117	IND(CO-AEFI)KEIDKZ1003	2021	60	FEMALE	HOSPITALIZED & RECOVERED	05-04-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
118	IND(CO-AEFI)MPCDWZ1001	2021	63	MALE	DEATH	17-03-2021	COVISHIELD	BILATERAL PNEUMONIA WITH RESPIRATORY FAILURE	C	22-Nov-21
119	IND(CO-AEFI)GOGONZ1014	2021	79	MALE	HOSPITALIZED & RECOVERED	31-03-2021	COVISHIELD	COVID 19 DISEASE WITH UNDERLYING DIABETES MELLITUS, HYPERTENSION, ISCHEMIC HEART DISEASE, CHRONIC KIDNEY DISEASE	C	22-Nov-21
120	IND(CO-AEFI)KABELZ1010	2021	62	FEMALE	DEATH	01-04-2021	COVISHIELD	COVID 19 PNEUMONIA WITH SEPSIS WITH RENAL FAILURE	C	22-Nov-21
121	IND(CO-AEFI)PBPTLZ1007	2021	64	MALE	SEVERE & RECOVERED	11-04-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
122	IND(CO-AEFI)MPSNIZ1005	2021	68	FEMALE	DEATH	22-03-2021	COVISHIELD	SEVERE COVID 19 PNEUMONIA	C	22-Nov-21
123	IND(CO-AEFI)GOGOSZ1011	2021	62	MALE	HOSPITALIZED & RECOVERED	26-03-2021	COVISHIELD	MILD COVID-19 PNEUMONIA	C	22-Nov-21
124	IND(CO-AEFI)PDYNMZ1001	2021	82	MALE	DEATH	08-03-2021	COVISHIELD	SEVERE ACUTE RESPIRATORY ILLNESS	C	22-Nov-21
125	IND(CO-AEFI)GOGOSZ1010	2021	58	FEMALE	HOSPITALIZED & RECOVERED	26-03-2021	COVISHIELD	MILD COVID 19 DISEASE	C	22-Nov-21
126	IND(CO-AEFI)GOGONZ1015	2021	55	MALE	HOSPITALIZED & RECOVERED	11-04-2021	COVISHIELD	ACUTE INFERIOR AND POSTERIOR WALL MYOCARDIAL INFARCTION	B1	22-Nov-21
127	IND(CO-AEFI)KEKZKZ1004	2021	44	FEMALE	HOSPITALIZED & RECOVERED	18-02-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
128	IND(CO-AEFI)WBASNZ1005	2021	37	MALE	HOSPITALIZED & RECOVERED	22-02-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
129	IND(CO-AEFI)KEAPZZ1020	2021	54	FEMALE	HOSPITALIZED & RECOVERED	08-03-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
130	IND(CO-AEFI)PBPTLZ1002	2021	53	FEMALE	SEVERE & RECOVERED	24-02-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
131	IND(CO-AEFI)PBPTLZ1003	2021	43	MALE	SEVERE & RECOVERED	26-02-2021	COVISHIELD	FACIAL PALSY	B2	22-Nov-21
132	IND(CO-AEFI)JKKUAZ1001	2021	21	MALE	DEATH	21-04-2021	COVISHIELD	ANAPHYLACTIC SHOCK	A1	22-Nov-21
133	IND(CO-AEFI)WBCALZ1028	2021	28	FEMALE	SEVERE & RECOVERED	19-04-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
134	IND(CO-AEFI)CGRNGZ1005	2021	46	FEMALE	HOSPITALIZED & RECOVERED	03-04-2021	COVISHIELD	ACUTE FEBRILE ILLNESS	A1	22-Nov-21
135	IND(CO-AEFI)UPBADZ1002	2021	55	MALE	DEATH	05-04-2021	COVISHIELD	HEPATITIS C WITH CHRONIC KIDNEY DISEASE	C	22-Nov-21
136	IND(CO-AEFI)WBDJLZ1013	2021	64	FEMALE	HOSPITALIZED & RECOVERED	06-04-2021	COVISHIELD	CHOLECYSTITIS WITH HYPERTENSION	C	22-Nov-21

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CAUSALITY CLASSIFICATION OF 178 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 22 NOV 2021- (NEW DELHI)

A1 - VACCINE PRODUCT RELATED REACTION

A2 - VACCINE QUALITY DEFECT RELATED REACTION

A3 - IMMUNIZATION ERROR RELATED REACTION

A4 - IMMUNIZATION ANXIETY RELATED REACTION

B1 - TEMPORAL RELATIONSHIP IS CONSISTENT BUT THERE IS INSUFFICIENT DEFINITIVE EVIDENCE FOR VACCINE CAUSING EVENT

B2 - REVIEWING FACTORS RESULT IN CONFLICTING TRENDS OF CONSISTENCY AND INCONSISTENCY WITH CAUSAL ASSOCIATION TO IMMUNIZATION

C - COINCIDENTAL - UNDERLYING OR EMERGING CONDITION(s), OR CONDITIONS CAUSED BY EXPOSURE TO SOMETHING OTHER THAN VACCINE

D - UNCLASSIFIABLE

SR. NO.	NATIONAL ID	YEAR	AGE (IN YEARS)	SEX	REASON FOR REPORTING/OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
137	IND(CO-AEFI)TRTRW21012	2021	57	FEMALE	HOSPITALIZED & RECOVERED	30-03-2021	COVISHIELD	SEIZURE DISORDER	C	22-Nov-21
138	IND(CO-AEFI)RJJPR21004	2021	48	MALE	HOSPITALIZED & RECOVERED	01-04-2021	COVISHIELD	ACUTE FEBRILE ILLNESS	A1	22-Nov-21
139	IND(CO-AEFI)KETHR21019	2021	70	FEMALE	HOSPITALIZED & RECOVERED	15-04-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
140	IND(CO-AEFI)GOGON21027	2021	78	FEMALE	DEATH	13-03-2021	COVISHIELD	COVID-19 DISEASE	C	22-Nov-21
141	IND(CO-AEFI)WBMNP21005	2021	24	FEMALE	HOSPITALIZED & RECOVERED	27-01-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
142	IND(CO-AEFI)WBAPD21005	2021	42	MALE	SEVERE & RECOVERED	22-02-2021	COVISHIELD	ALLERGIC RASH	A1	22-Nov-21
143	IND(CO-AEFI)KEPLK21013	2021	42	FEMALE	HOSPITALIZED & RECOVERED	21-05-2021	COVISHIELD	SEIZURE DISORDER IN POST-OPERATIVE MENINGIOMA WITH REOCCURRENCE	C	22-Nov-21
144	IND(CO-AEFI)DLSDR21002	2021	28	MALE	HOSPITALIZED & RECOVERED	05-05-2021	COVISHIELD	ACUTE IDIOPATHIC THROMBOCYTOPENIC PURPURA	B1	22-Nov-21
145	IND(CO-AEFI)TNCNI21016	2021	50	FEMALE	DEATH	07-04-2021	COVISHIELD	COVID-19 DISEASE (PNEUMONIA, ACUTE RESPIRATORY DISTRESS SYNDROME, SEPSIS, ACUTE KIDNEY INJURY AND TYPE 1 RESPIRATORY FAILURE)	C	22-Nov-21
146	IND(CO-AEFI)GOGON21033	2021	65	FEMALE	HOSPITALIZED & RECOVERED	28-05-2021	COVISHIELD	ANTERIOR WALL MYOCARDIAL INFARCTION WITH HYPERTENSION	C	22-Nov-21
147	IND(CO-AEFI)TSRGY21005	2021	49	MALE	HOSPITALIZED & RECOVERED	12-04-2021	COVISHIELD	IDIOPATHIC THROMBOCYTOPENIC PURPURA	B1	22-Nov-21
148	IND(CO-AEFI)TSHYD21022	2021	18	FEMALE	DEATH	29-05-2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME .	A1	22-Nov-21
149	IND(CO-AEFI)ORRYG21005	2021	19	FEMALE	HOSPITALIZED & RECOVERED	08-06-2021	COVISHIELD	ALLERGIC REACTION, VOMITTING AND PAIN IN ABDOMEN	A1	22-Nov-21
150	IND(CO-AEFI)HAPNP21008	2021	20	MALE	HOSPITALIZED & RECOVERED	21-06-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
151	IND(CO-AEFI)GUSBK21001	2021	25	MALE	HOSPITALIZED & RECOVERED	24-06-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
152	IND(CO-AEFI)MEEKH21004	2021	19	FEMALE	HOSPITALIZED & RECOVERED	14-06-2021	COVISHIELD	FOCAL SEIZURE	B1	22-Nov-21
153	IND(CO-AEFI)KEPLK21017	2021	53	FEMALE	HOSPITALIZED & RECOVERED	29-06-2021	COVISHIELD	ANXIETY REACTION	A4	22-Nov-21
154	IND(CO-AEFI)RJJPR21015	2021	43	FEMALE	HOSPITALIZED & RECOVERED	02-07-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
155	IND(CO-AEFI)MHBMC21099	2021	51	FEMALE	DEATH	03-04-2021	COVISHIELD	SEVERE COVID PNEUMONIA	C	22-Nov-21
156	IND(CO-AEFI)UPPSN21002	2021	58	FEMALE	HOSPITALIZED & RECOVERED	08-07-2021	COVISHIELD	SEIZURE IN A KNOWN CASE OF CVA AND HYPERTENSION	C	22-Nov-21
157	IND(CO-AEFI)WBCAL21032	2021	37	FEMALE	HOSPITALIZED & RECOVERED	26-06-2021	COVISHIELD	ACUTE FEBRILE ILLNESS WITH VOMITING	A1	22-Nov-21
158	IND(CO-AEFI)UPRBL21002	2021	77	MALE	DEATH	17-03-2021	COVISHIELD	COVID 19 PNEUMONIA	C	22-Nov-21
159	IND(CO-AEFI)UPGZA21001	2021	85	MALE	DEATH	09-04-2021	COVISHIELD	SEVERE COVID 19 PNEUMONIA	C	22-Nov-21
160	IND(CO-AEFI)GUJMD21003	2021	22	MALE	HOSPITALIZED & RECOVERED	14-04-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
161	IND(CO-AEFI)KETHR21032	2021	58	FEMALE	HOSPITALIZED & RECOVERED	06-07-2021	COVAXIN	LEFT FOCAL SEIZURES (RIGHT FRONTAL MENINGIOMA) IN A KNOWN CASE OF CARCINOMA THYROID AND HYPOTHYROIDISM	C	22-Nov-21
162	IND(CO-AEFI)KETRM21027	2021	21	FEMALE	HOSPITALIZED & RECOVERED	03-07-2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	22-Nov-21
163	IND(CO-AEFI)MHTHN21019	2021	36	FEMALE	HOSPITALIZED & RECOVERED	19-03-2021	COVISHIELD	ACUTE DISSEMINATED ENCEPHALOMYELITIS	B1	22-Nov-21
164	IND(CO-AEFI)MHBMC21059	2021	22	MALE	HOSPITALIZED & RECOVERED	29-06-2021	COVISHIELD	SEIZURE	B1	22-Nov-21
165	IND(CO-AEFI)WBNPG21008	2021	62	FEMALE	HOSPITALIZED & RECOVERED	22-05-2021	COVISHIELD	EXFOLIATIVE DERMATITIS WITH SEPSIS WITH URINARY TRACT INFECTION WITH DIABETES MELLITUS WITH HYPERTENSION WITH HYPOTHYROIDISM	B2	22-Nov-21
166	IND(CO-AEFI)WBCAL21033	2021	25	FEMALE	HOSPITALIZED & RECOVERED	22-07-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
167	IND(CO-AEFI)HAJJR21003	2021	31	FEMALE	HOSPITALIZED & RECOVERED	25-01-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
168	IND(CO-AEFI)KETHR21035	2021	23	FEMALE	HOSPITALIZED & RECOVERED	15-07-2021	COVISHIELD	SEIZURE DISORDER? ECLAMPSIA	C	22-Nov-21
169	IND(CO-AEFI)UPGBN21004	2021	47	MALE	DEATH	15-04-2021	COVISHIELD	COVID 19 DISEASE	C	22-Nov-21

CAUSALITY CLASSIFICATION OF 178 AEFI CASES APPROVED BY THE NATIONAL AEFI COMMITTEE ON 22 NOV 2021- (NEW DELHI)

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SR.	PATIENT ID	YEAR	AGE IN YEARS	SEX	REASON FOR REPORTING/OUTCOME	DATE OF VACCINATION (DD/MM/YYYY)	VACCINE	DIAGNOSIS	CLASSIFICATION BY NATIONAL AEFI COMMITTEE	DATE OF APPROVAL BY NATIONAL AEFI COMMITTEE
170	IND(CO-AEFI)KETRM21031	2021	56	MALE	HOSPITALIZED & RECOVERED	01-08-2021	COVISHIELD	NON-ST-ELEVATION MYOCARDIAL INFARCTION with AGE-56 YEARS and RISK FACTORS OF SMOKING, ALCOHOL CONSUMPTION WITH FAMILY HISTORY.	C	22-Nov-21
171	IND(CO-AEFI)KEWYD21019	2021	37	MALE	HOSPITALIZED & RECOVERED	19-07-2021	COVISHIELD	ACUTE ANTERIOR WALL MYOCARDIAL INFARCTION	B1	22-Nov-21
172	IND(CO-AEFI)MHBMC21066	2021	19	FEMALE	HOSPITALIZED & RECOVERED	30-07-2021	COVISHIELD	ACUTE FEBRILE ILLNESS	A1	22-Nov-21
173	IND(CO-AEFI)WBDJL21034	2021	32	MALE	SEVERE & RECOVERED	09-08-2021	COVISHIELD	ANAPHYLAXIS	A1	22-Nov-21
174	IND(CO-AEFI)PDPNY21006	2021	20	MALE	HOSPITALIZED & RECOVERED	17-06-2021	COVISHIELD	GUILLAIN BARRE SYNDROME	B1	22-Nov-21
175	IND(CO-AEFI)KEPTM21011	2021	51	FEMALE	HOSPITALIZED & RECOVERED	14-08-2021	COVISHIELD	ALLERGIC BRONCHITIS	C	22-Nov-21
176	IND(CO-AEFI)DLNWE21006	2021	24	FEMALE	HOSPITALIZED & RECOVERED	06-08-2021	COVISHIELD	ALLERGIC REACTION	A1	22-Nov-21
177	IND(CO-AEFI)MPSDL21001	2021	51	MALE	SEVERE & RECOVERED	01-04-2021	COVISHIELD	FOCAL SEIZURE	B1	22-Nov-21
178	IND(CO-AEFI)KEAPZ21040	2021	28	FEMALE	DEATH	07-06-2021	COVISHIELD	THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME	A1	22-Nov-21

*Covid vaccine is a new vaccine. The causality may change as more information become available.

Verified by Dr Anil Gurtoo and Dr Anju Seth on 01 Dec 2021

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FTS - 33825536

By Speed Post

No. Z.33013/263/2021-CVAC
Government of India
Ministry of Health & Family Welfare
(COVID-19 Vaccine Administration Cell)

Room No 311, D Wing,
Nirman Bhawan, New Delhi-110 108
Dated: 17th December, 2021

Sub: First Appeal bearing Registration No. MOHFW/A/E/21/00872 dated 22.11.2021 filed by Mr. Pavan Omtri, Plot 405 A, Road 22A, Jubilee Hills, Hyderabad, Telangana- 500033, received online through RTI portal on 22.11.2021 under RTI Act, 2005-reg.

1. **Background and Grounds of the Appeal**

19.10.2021: RTI application bearing Registration No.MOHFW/R/E/21/06320 dated 19.10.2021 filed online by Mr. Pavan Omtri, Plot 405 A, Road 22A, Jubilee Hills, Hyderabad, Telangana-500033, under RTI Act, 2005 was received in the COVID-19 Vaccine Administration Cell (CVAC) on 19.10.2021.

29.10.2021: US & CPIO (CVAC) transferred the aforesaid RTI application dated 19.10.2021 to US & CPIO (Immunization), being link officer to US & CPIO (CVAC), as the officer was in an official training programme during that period.

22.11.2021: As no information in respect of the RTI application dated 19.10.2021 were shared by the CPIO within the stipulated time period, the applicant has filed an online appeal bearing Registration No. MOHFW/A/E/21/00872 dated 22.11.2021 and the same was received in the CVAC on 22.11.2021.

2. The Appeal has been filed by Mr. Pavan Omtri, on the grounds that 'No Response Within the Time Limit' from the CPIO in respect of information sought vide RTI application dated 19.10.2021 received in the Division on 19.10.2021 under the RTI Act 2005.

Deliberation and Order:

3. The online RTI Application dated 19.10.2021 received in this Division on 19.10.2021 and Appeal dated 22.11.2021 received in this Division on 22.11.2021 have been perused. Ongoing through the application, prima facie it appears that the applicant requires information on the following:

> ***Detailed analysis and reports of the AEFI investigations done by the central authority on the death of an 18-year-old girl from Hyderabad, Telangana, Ms. Rithaika Sri Omtri, a post vaccination event case Vaccine: Covidshield Date of Vaccination: May 29th, 2021***
>
> ***We are requesting information on these following specific items pertaining to above case:***
>
> ***1. Investigation reports of the above case given by Government Officials.***
>
> ***2. Basis for conclusions in the above case.***
>
> ***3. Date-wise procedure carried out by you to perform investigation of above case.***

(116)

4. Whether the conclusion on the above case has been made. If so, please provide copy of those documents.

As per the information available with the COVID-19 Vaccine Administration Cell (CVAC), following is informed:

As per the COVID 19 operational guideline, the Case Reporting Form (CRF) and the Case Investigation Form (CIF) along with the relevant case records (hospital records or post mortem report or verbal autopsy report in case of death cases) for all suspected serious/severe AEFI cases are to be filled/collected and submitted by the District Immunization Officer to the District AEFI committee. These are also uploaded on the CoWIN portal. Since the investigation is the function of the DIO and district AEFI committee, these documents may be sought from the concerned district authorities.

The reporting and investigation formats were received on 22nd June, 2021. Supporting case investigation reports such as PM/verbal autopsy, CT Scan & MRI report were received on 4th October, 2021 and hospital records were received on 22nd October, 2021 through CoWIN. These records were initially screened on 8th October, 2021 and are the causality assessment was approved on 22nd November, 2021 by the Member Expert of the National AEFI Committee.

The causality of the case has been approved with a diagnosis of THROMBOSIS with THROMBOCYTOPENIA SYNDROME and has been classified as A1-VACCINE PRODUCT RELATED REACTION. The result of the case can be accessed by using the link - https://main.mohfw.gov.in/Organisation/Departments-of-Health-and-Family-Welfare/immunization/aefi-reports

5. With regard to the concerns of the applicant that no response was received from CPIO within the stipulated time period. In this context, US & CPIO (CVAC) is suggested that such type of delay to be avoided in future. US & CPIO (CVAC) to ensure that information with regard to any RTI application is disposed of within the stipulated time period.

6. The appeal stands disposed of in above terms.

7. In case the appellant intends to prefer an appeal under section 19(3) of the RTI Act, 2005, you may approach the Central Information Commission (CIC), Baba Gangnath Marg, Munirka, New Delhi-110067 within 90 days from the date of receipt of this decision.

17/12/21

(Sachin Kumar)
First Appellate Authority (CVAC)

To

Mr. Pavan Omtri,
Plot 405 A Road 22A Jubilee Hills Hyderabad,
Telangana 500033

Copy to:

1. US & CPIO (CVAC), MOHFW, New Delhi

EXHIBIT I (117)

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JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, July 2, 2012

GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data

Largest Health Care Fraud Settlement in U.S. History

Global health care giant GlaxoSmithKline LLC (GSK) agreed to plead guilty and to pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices, the Justice Department announced today. The resolution is the largest health care fraud settlement in U.S. history and the largest payment ever by a drug company.

GSK agreed to plead guilty to a three-count criminal information, including two counts of introducing misbranded drugs, Paxil and Wellbutrin, into interstate commerce and one count of failing to report safety data about the drug Avandia to the Food and Drug Administration (FDA). Under the terms of the plea agreement, GSK will pay a total of $1 billion, including a criminal fine of $956,814,400 and forfeiture in the amount of $43,185,600. The criminal plea agreement also includes certain non-monetary compliance commitments and certifications by GSK's U.S. president and board of directors. GSK's guilty plea and sentence is not final until accepted by the U.S. District Court.

GSK will also pay $2 billion to resolve its civil liabilities with the federal government under the False Claims Act, as well as the states. The civil settlement resolves claims relating to Paxil, Wellbutrin and Avandia, as well as additional drugs, and also resolves pricing fraud allegations.

"Today's multi-billion dollar settlement is unprecedented in both size and scope. It underscores the Administration's firm commitment to protecting the American people and holding accountable those who commit health care fraud," said James M. Cole, Deputy Attorney General. "At every level, we are determined to stop practices that jeopardize patients' health, harm taxpayers, and violate the public trust – and this historic action is a clear warning to any company that chooses to break the law."

"Today's historic settlement is a major milestone in our efforts to stamp out health care fraud," said Bill Corr, Deputy Secretary of the Department of Health and Human Services (HHS). "For a long time, our health care system had been a target for cheaters who thought they could make an easy profit at the expense of public safety, taxpayers, and the millions of Americans who depend on programs like Medicare and Medicaid. But thanks to strong enforcement actions like those we have announced today, that equation is rapidly changing."

This resolution marks the culmination of an extensive investigation by special agents from HHS-OIG, FDA and FBI, along with law enforcement partners across the federal government. Moving forward, GSK will be subject to stringent requirements under its corporate integrity agreement with HHS-OIG; this agreement is designed to increase accountability and transparency and prevent future fraud and abuse. Effective law enforcement partnerships and fraud prevention are hallmarks of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which fosters government collaboration to fight fraud.

Criminal Plea Agreement

Under the provisions of the Food, Drug and Cosmetic Act, a company in its application to the FDA must specify each intended use of a drug. After the FDA approves the product as safe and effective for a specified use, a company's promotional activities must be limited to the intended uses that FDA approved. In fact, promotion by the manufacturer for other uses – known as "off-label uses" – renders the product "misbranded."

Paxil: In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misreported that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United States alleges, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a "black box warning" stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18.

Wellbutrin: The United States also alleges that, from January 1999 to December 2003, GSK promoted Wellbutrin, approved at that time only for Major Depressive Disorder, for weight loss, the treatment of sexual dysfunction, substance addictions and Attention Deficit Hyperactivity Disorder, among other off-label uses. The United States contends that GSK paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted and also used sales representatives, sham advisory boards, and supposedly independent Continuing Medical Education (CME) programs to promote Wllbutrin for these unapproved uses. GSK has agreed to plead guilty to misbranding Wellbutrin in that its labeling did not bear adequate directions for these off-label uses. For the Paxil and Wellbutrin misbranding offenses, GSK has agreed to pay a criminal fine and forfeiture of $757,387,200.

Avandia: The United States alleges that, between 2001 and 2007, GSK failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends. The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia. Since 2007, the FDA has added two black box warnings to the Avandia label to alert physicians about the potential increased risk of (1) congestive heart failure, and (2) myocardial infarction (heart attack). GSK has agreed to plead guilty to failing to report data to the FDA and has agreed to pay a criminal fine in the amount of $242,612,800 for its unlawful conduct concerning Avandia.

"This case demonstrates our continuing commitment to ensuring that the messages provided by drug manufacturers to physicians and patients are true and accurate and that decisions as to what drugs are prescribed

to sick patients are based on best medical judgments, not false and misleading claims or improper financial inducements," said Carmen Ortiz, U.S. Attorney for the District of Massachusetts.

"Patients rely on their physicians to prescribe the drugs they need," said John Walsh, U.S. Attorney for Colorado. "The pharmaceutical industries' drive for profits can distort the information provided to physicians concerning drugs. This case will help to ensure that your physician will make prescribing decisions based on good science and not on misinformation, money or favors provided by the pharmaceutical industry."

Civil Settlement Agreement

As part of this global resolution, GSK has agreed to resolve its civil liability for the following alleged conduct: (1) promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; (2) making false and misleading statements concerning the safety of Avandia; and (3) reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

Off-Label Promotion and Kickbacks: The civil settlement resolves claims set forth in a complaint filed by the United States alleging that, in addition to promoting the drugs Paxil and Wellbutrin for unapproved, non-covered uses, GSK also promoted its asthma drug, Advair, for first-line therapy for mild asthma patients even though it was not approvedor medically appropriate under these circumstances. GSK also promoted Advair for chronic obstructive pulmonary disease with misleading claims as to the relevant treatment guidelines. The civil settlement also resolves allegations that GSK promoted Lamictal, an anti-epileptic medication, for off-label, non-covered psychiatric uses, neuropathic pain and pain management. It further resolves allegations that GSK promoted certain forms of Zofran, approved only for post-operative nausea, for the treatment of morning sickness in pregnant women. It also includes allegations that GSK paid kickbacks to health care professionals to induce them to promote and prescribe these drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex. The United States alleges that this conduct caused false claims to be submitted to federal health care programs.

GSK has agreed to pay $1.043 billion relating to false claims arising from this alleged conduct. The federal share of this settlement is $832 million and the state share is $210 million.

This off-label civil settlement resolves four lawsuits pending in federal court in the District of Massachusetts under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery.

Avandia: In its civil settlement agreement, the United States alleges that GSK promoted Avandia to physicians and other health care providers with false and misleading representations about Avandia's safety profile, causing false claims to be submitted to federal health care programs. Specifically, the United States alleges that GSK stated that Avandia had a positive cholesterol profile despite having no well-controlled studies to support that message. The United States also alleges that the company sponsored programs suggesting cardiovascular benefits from Avandia therapy despite warnings on the FDA-approved label regarding cardiovascular risks. GSK has agreed to pay $657 million relating to false claims arising from misrepresentations about Avandia. The federal share of this settlement is $508 million and the state share is $149 million.

Price Reporting: GSK is also resolving allegations that, between 1994 and 2003, GSK and its corporate predecessors reported false drug prices, which resulted in GSK's underpaying rebates owed under theMedicaid

Drug Rebate Program. By law, GSK was required to report the lowest, or "best" price that it charged its customers and to pay quarterly rebates to the states based on those reported prices. When drugs are sold to purchasers in contingent arrangements known as "bundles," the discounts offered for the bundled drugs must be reallocated across all products in the bundle proportionate to the dollar value of the units sold. The United States alleges that GSK had bundled sales arrangements that included steep discounts known as "nominal" pricing and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to the Department of Health and Human Services. Had it done so, the effective prices on certain drugs would have been different, and, in some instances, triggered a new, lower best price than what GSK reported. As a result, GSK underpaid rebates due to Medicaid and overcharged certain Public Health Service entities for its drugs, the United States contends. GSK has agreed to pay $300 million to resolve these allegations, including $160,972,069 to the federal government, $118,792,931 to thestates, and $20,235,000 to certain Public Health Service entities who paid inflated prices for the drugs at issue.

Except to the extent that GSK has agreed to plead guilty to the three-count criminal information, the claims settled by these agreements are allegations only, and there has been no determination of liability.

"This landmark settlement demonstrates the Department's commitment to protecting the American public against illegal conduct and fraud by pharmaceutical companies," said Stuart F. Delery, Acting Assistant Attorney General for the Justice Department's Civil Division. "Doctors need truthful, fair, balanced information when deciding whether the benefits of a drug outweigh its safety risks. By the same token, the FDA needs all necessary safety-related information to identify safety trends and to determine whether a drug is safe and effective. Unlawful promotion of drugs for unapproved uses and failing to report adverse drug experiences to the FDA can tip the balance of those important decisions, and the Justice Department will not tolerate attempts by those who seek to corrupt our health care system in this way."

Non-monetary Provisions and Corporate Integrity Agreement

In addition to the criminal and civil resolutions, GSK has executed a five-year Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The plea agreement and CIA include novel provisions that require that GSK implement and/or maintain major changes to the way it does business, including changing the way its sales force is compensated to remove compensation based on sales goals for territories, one of the driving forces behind much of the conduct at issue in this matter. Under the CIA, GSK is required to change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. GSK may recoup monies from executives who are current employees and those who have left the company. Among other things, the CIA also requires GSK to implement and maintain transparency in its research practices and publication policies and to follow specified policies in its contracts with various health care payors.

"Our five-year integrity agreement with GlaxoSmithKline requires individual accountability of its board and executives," said Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services. "For example, company executives may have to forfeit annual bonuses if they or their subordinates engage in significant misconduct, and sales agents are now being paid based on quality of service rather than sales targets."

"The FDA Office of Criminal Investigations will aggressively pursue pharmaceutical companies that choose to put profits before the public's health," said Deborah M. Autor, Esq., Deputy Commissioner for Global Regulatory Operations and Policy, U.S. Food and Drug Administration. "We will continue to work with the Justice Department and our law enforcement counterparts to target companies that disregard the protections of the drug approval

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process by promoting drugs for uses when they have not been proven to be safe and effective for those uses, and that fail to report required drug safety information to the FDA."

"The record settlement obtained by the multi-agency investigative team shows not only the importance of working with our partners, but also the importance of the public providing their knowledge of suspect schemes to the government," said Kevin Perkins, Acting Executive Assistant Director of the FBI's Criminal, Cyber, Response and Services Branch. "Together, we will continue to bring to justice those engaged in illegal schemes that threaten the safety of prescription drugs and other critical elements of our nation's healthcare system."

" Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

"Today's announcement illustrates the efforts of VA OIG and its law enforcement partners in ensuring the integrity of the medical care provided our nation's veterans by the Department of Veterans Affairs," said George J. Opfer, Inspector General of the Department of Veterans Affairs. "The monetary recoveries realized by VA in this settlement will directly benefit VA healthcare programs that provide for veterans' continued care."

"This settlement sends a clear message that taking advantage of federal health care programs has substantial consequences for those who try," said Rafael A. Medina, Special Agent in Charge of the Northeast Area Office of Inspector General for the U.S. Postal Service. "The U.S. Postal Service pays more than one billion dollars a year in workers' compensation benefits and our office is committed to pursuing those individuals or entities whose fraudulent acts continue to unfairly add to that cost."

A Multilateral Effort

The criminal case is being prosecuted by the U.S. Attorney's Office for the District of Massachusetts and the Civil Division's Consumer Protection Branch. The civil settlement was reached by the U.S. Attorney's Office for the District of Massachusetts, the U.S. Attorney's Office for the District of Colorado and the Civil Division's Commercial Litigation Branch. Assistance was provided by the HHS Office of Counsel to the Inspector General, Office of the General Counsel-CMS Division and FDA's Office of Chief Counsel as well as the National Association of Medicaid Fraud Control Units.

This matter was investigated by agents from the HHS-OIG; the FDA's Office of Criminal Investigations; the Defense Criminal Investigative Service of the Department of Defense; the Office of the Inspector General for the Office of Personnel Management; the Department of Veterans Affairs; the Department of Labor; TRICARE Program Integrity; the Office of Inspector General for the U.S. Postal Service and the FBI.

This resolution is part of the government's emphasis on combating health care fraud and another step for the Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative, which was announced in May 2009 by Attorney General Eric Holder and Kathleen Sebelius, Secretary of HHS. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid financial fraud through enhanced cooperation. Over the last three years, the department has recovered a total of more than $10.2 billion in

settlements, judgments, fines, restitution, and forfeiture in health care fraud matters pursued under the False Claims Act and the Food, Drug and Cosmetic Act.

Court documents related to today's settlement can be viewed online at www.justice.gov/opa/gsk-docs.html .

Related Materials:

Remarks by the Deputy Attorney General James M. Cole at the GSK Press Conference
Remarks by Acting Assistant Attorney General for the Civil Division Stuart F. Delery at the GSK Press Conference

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Topic(s):
Consumer Protection

Component(s):
Civil Division

Press Release Number:
12-842

Updated May 22, 2015

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IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

WRIT PETITION (C) NO. _____ / 2022

DISTRICT:- AURANGABAD

In the matter of admission by the Government's AEFI Committee that the death of Petitioner's daughter Dr. Snehal Lunawat due to side effects of vaccines;

And

In the matter of giving directions from proper prosecutions to prevent further loss of lives;

And

In the matter of directions for granting compensation to the petitioner and his family.

Shri. Dilip Lunawat)
)
)
)

..... Petitioner

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1. Serum Institute of India Pvt. Ltd.)
Mr. Adar C. Poonawalla (CEO))
212/2, Soli Poonawalla Rd, JJC Colony,)
Suryalok Nagari, Hadapsar,)
Pune, Maharashtra 411 028.)

2. Bill Gates)
Partner of Serum Institute,)
For manufacturing Covishield,)
Having address at:)
212/2, Soli Poonawalla Rd, JJC Colony,)
Suryalok Nagari, Hadapsar,)
Pune, Maharashtra 411 028.)

3. Union of India)
Through Chief Secretary)
To the Government of India)
New Delhi 1100 01.)

4. State of Maharashtra)
Through Chief Secretary,)
Maharashtra State,)
Mantralaya, Mumbai – 400 023.)

5. Ministry of Health & Family Welfare)
Government of India)
Room No. 348; 'A' Wing,)
Nirman Bhavan,)
New Delhi-110 011.)

6. Drug Controller General of India)
FDA Bhawan, Kotla Road,)
New Delhi 110 002.)

7. Dr. V.G. Somani)
Drug Controller General of India)
DA Bhawan, Kotla Road,)
New Delhi 110 002.)

8. Dr. Randeep Guleria)
Director, AIIMS, New Delhi.)
Director, AIIMS, New Delhi.)
All India Institute of Medical Sciences)
Ansari Nagar, New Delhi – 110 029.)

..... Respondents

To,
The Registrar Civil Side,
High Court,
Mumbai.

Sir,

I, **Shri. Dilip Lunawat** the Petitioner above named, do hereby appoint jointly and severally **Adv. Abhishek Mishra & Adv. Deepika G. Jaiswal,** Advocate, Bombay High Court, to act, appear and plead for me in the above matter.

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IN WITNESS WHEREOF, we have hereunto set and subscribed our respective hands to this writing on this 25th January, 2022.

Accepted:

Petitioner

Shri. Dilip Lunawat

Adv. Abhishek Mishra (I-23675)

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MAH/890/2020

IN THE HIGH COURT OF JUDICATURE

AT BOMBAY

CIVIL APPELLATE JURISDICTION

WRIT PETITION (C) NO. _____ / 2022

Shri. Dilip Lunawat

....Petitioner

Versus

State of Maharashtra & Ors.

....Respondents

VAKALATNAM

Date: 28th Day of January, 2022

Adv. Abhishek Mishra (I-23675)

Adv. Deepika G. Jaiswal (I-30967)

Advocate for Petitioner

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IN THE HIGH COURT OF JUDICATURE

AT BOMBAY

CIVIL APPELLATE JURISDICTION

WRIT PETITION (C) NO. _____ / 2022

Shri. Dilip Lunawat

....Petitioner

Versus

State of Maharashtra & Ors.

....Respondents

WRIT PETITION

Date: 25 Day of January, 2022

Adv. Abhishek Mishra (I-23675)

Adv. Deepika G. Jaiswal (I-30967)

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